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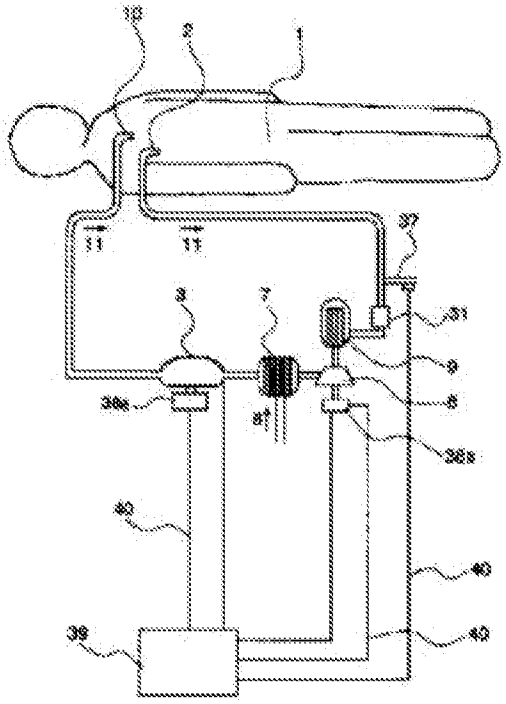
(54) EXTRACORPOREAL CIRCULATION APPARATUS HAVING CONTROL FUNCTION

(57)Abstract:

PROBLEM TO BE SOLVED: To provide an extracorporeal circulation apparatus which is simple and is automatically controllable and low-invasive and is simple in constitution.

SOLUTION: The extracorporeal circulation apparatus which is arranged with prescribed elements within circuits to cause the extracorporeal circulation of blood has a blood pump 6, a blood reservoir 3 having a volume adjusting means for actively increasing and decreasing the volume to be stored and a volume detecting means for detecting the volume and a control means 39 which is supplied with the output of this volume detecting means, controls the volume of the blood reservoir and controls the flow rate of the blood pump with the volume adjusting means. The apparatus is so constituted that the adjustment of the circulation state in the circuits is made possible by controlling at least the volume adjusting means.



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CLAIMS

[Claim(s)]
[Claim 1]Extracorporeal circulation equipment constituted so that it might have the following, a predetermined element might be arranged in a circuit which controls said capacity regulation means by said control means at least, and is characterized by constituting so that it may be possible to adjust a circulation state in a circuit by it and extracorporeal circulation of the blood might be carried out.
A blood pump.
A blood reservoir which has a capacity detection means for detecting a capacity regulation means for fluctuating capacity to store actively, and said capacity.
A control means which controls a flow of said blood pump while an output of said capacity detection means is supplied and controlling capacity of said blood reservoir via said capacity regulation means.

[Claim 2]The extracorporeal circulation equipment according to claim 1 which is provided with a circulation state detection means which detects a circulation state in a circuit and with which a control means adjusts a circulation state in said circuit according to an output which said circulation state detection means detected.
[Claim 3]The extracorporeal circulation equipment according to claim 1 or 2 whose blood pump is a non-positive-displacement-design blood pump.
[Claim 4]A blood reservoir has **** external housing for a blood chamber which stores blood, and its blood chamber, The extracorporeal circulation equipment according to any one of claims 1 to 3 which said blood chamber is a complete rebreathing system with which the indoor blood does not meet with the open air, and was constituted so that a capacity regulation means might adjust capacity by changing at least some outer walls of said blood chamber.
[Claim 5]It has **** external housing for a blood chamber in which a blood reservoir stores

blood, pressure control chambers which adjust blood volume in said blood chamber which adjoined and provided in the blood chamber, and these two rooms, and the indoor blood of said blood chamber is a complete rebreathing system which does not meet with the open air. The extracorporeal circulation equipment according to any one of claims 1 to 3 constituted so that a capacity regulation means might adjust capacity by changing at least some outer walls of said blood chamber.

[Claim 6]The extracorporeal circulation equipment according to claim 4 or 5 constituted so that a capacity detection means might detect blood volume of a blood chamber based on a deformed state of an outer wall of a blood chamber.
[Claim 7]The extracorporeal circulation equipment according to any one of claims 4 to 6 with which at least a part of blood chamber was formed of a diaphragm which is a flexible septum.
[Claim 8]The extracorporeal circulation equipment according to claim 7 which adjusts capacity of a blood chamber when a capacity regulation means has a pusher plate which consists of a hard board and the pusher plate presses or tows a septum.
[Claim 9]The extracorporeal circulation equipment according to any one of claims 3 to 8 with which a non-positive displacement type pump is installed in a circuit only at the upstream of a blood reservoir.
[Claim 10]The extracorporeal circulation equipment according to claim 2 whose circulation state detection means is the pressure sensor formed in an inflow part.
[Claim 11]The extracorporeal circulation equipment according to claim 2 constituted so that a circulation state detection means might detect a circulation state based on an output of the consumed electric current and/or a power consumption monitor which were connected to a drive of a blood pump.
[Claim 12]Claim 2 which has a circulation state estimation means by which a circulation state detection means presumes a living body's arterial pressure and/or an extracorporeal circulation blood flow rate based on data obtained from the inside of a circuit, extracorporeal circulation equipment given in either 10 or 11.
[Claim 13]Claim 2 controlled to lower number of rotations of a blood pump, or to lower capacity of a blood reservoir when a blood removal part inhales a control means based on information acquired from a circulation state detection means, **** is detected and it is detected with this ****, or extracorporeal circulation equipment given in either 10-12.
[Claim 14]Claim 2 which has a means to set up a preset value which shows a range which serves as a critical value or a target about information acquired from a circulation state detection means, and a control means is based [Claim 2] on comparison of said information and said preset value, and increases or decreases an extracorporeal circulation flow of blood, or extracorporeal circulation equipment given in either 10-13.

[Claim 15]At least by one side of operation which raises number of rotations of a blood pump, or lowers capacity of a blood reservoir, perform an increase in an extracorporeal circulation flow and reduction of said extracorporeal circulation flow, The extracorporeal circulation equipment according to claim 14 performed at least by one side of operation which lowers number of rotations of said pump, or raises capacity of said blood reservoir.
[Claim 16]The extracorporeal circulation equipment according to any one of claims 1 to 15 provided with a means to make a circulation system generate pulsatile flow by making number of rotations of a blood pump fluctuate periodically.
[Claim 17]The extracorporeal circulation equipment according to any one of claims 1 to 16 provided with a means to make a circulation system generate pulsatile flow thru/or vibration by making capacity of a blood reservoir fluctuate periodically.
[Claim 18]The extracorporeal circulation equipment according to any one of claims 1 to 17 which assembled a blood pump, a blood reservoir, an artificial lung, and a filter in one, and constituted them at least among elements arranged in a circuit.
[Claim 19]The extracorporeal circulation equipment comprising according to any one of claims 1 to 18:
An aeration detection means to detect an aeration arranged at an inflow part of a circuit.
A means to perform at least one side among generating of an alarm, and automatic stay of a pump when it operates according to an output of said aeration detection means and mixing of air into a circuit is detected.

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DETAILED DESCRIPTION

[Detailed Description of the Invention]
[0001]
[Field of the Invention]this invention was provided with the extracorporeal circulation equipment of blood, and the function which controls a circulation state especially -- simple -- low -- it is related with invasion extracorporeal circulation equipment.
[0002]
[Description of the Prior Art]In the operation of the heart and a large artery, in order to change the heart temporarily into the state near a stop or a stop and to make the function of the heart and a lung take over with a machine, extracorporeal circulation equipment is used. The extracorporeal circulation equipment currently used conventionally is composition which was provided with the blood removal pipe 2, the blood reservoir 83, the heat exchanger 5, the main pump 86, the artificial lung 7, the filter 9, and the blood transfusion pipe 10, and has arranged those elements one by one all over blood circuits as main elements, as shown in drawing 8.
[0003]The blood removal pipe 2 is inserted in the patient's 1 up-and-down vena cava and right atrium, and in order to take many flows, a thick thing is used as much as possible. As for the blood reservoir 83, many open sand molds with which blood touches air are used.
By fall blood removal which used the fall of the blood reservoir 83 with the patient 1, blood flows through a blood removal pipe.
Although it is a small number, the blood reservoir of the enclosed type with which blood does not touch air is also used, and there are some into which blood flows through a blood removal pipe by compulsive blood removal using a blood pump. In the blood reservoir of an open sand mold, since a risk of sending in air in a circuit will increase if the blood volume which stored liquid falls, there are some which emit an alarm, but what adjusts capacity actively is not known. The heat exchanger 5 is installed in a blood reservoir in many cases, carries out perfusion of the liquid (usually tap water) warmed thru/or cooled by metal tubes with the

heating-cooling equipment 4, and warms thru/or cools blood. A roller pump or a centrifugal pump is used and the main pump 86 is installed downstream from the blood reservoir. The example currently installed upstream of the blood reservoir does not have a main pump. The whole extracorporeal circulation equipment is large-sized, and needs to secure a large space compared with a general operation. It is not suitable for carrying for a large-sized machine, and is always installed in the space undergoing an operation.

[0004]Operation of extracorporeal circulation equipment is performed by stationing the special staff for it. Although an extracorporeal circulation engineer takes on the duties, a medical practitioner may usually perform an extracorporeal circulation operator. Anyway, the special staff who acquired advanced technology is required. An extracorporeal circulation operator is located beside an operating table, does not join operation or is never located in a remote place. The extracorporeal circulation operator is performing adjustment of the capacity of a blood reservoir, or a pump flow rate by manual operation in consideration of the optimum extracorporeal circulation blood flow rate, looking at the grade of blood removal, and a living body's arterial pressure. Therefore, an extracorporeal circulation operator cannot separate from extracorporeal circulation equipment during extracorporeal circulation enforcement.

[0005]By the way, in order to utilize a human and economical medical resource effectively, in the surgery field, the no-touch isolation technique is introduced positively. The no-touch isolation technique in a cardiovascular surgery field is called MICS (Minimally Invasive Cardiac Surgery; low invasion heart surgery). In MICS, in order to reduce invasion, median sternotomy covering an overall length is not performed, but skin incision is shortened as much as possible. Therefore, the view for exposing the heart is restricted. Therefore, the thin thing from which the blood removal pipe used for extracorporeal circulation equipment does not become the hindrance of a view is liked.

[0006]

[Problem to be solved by the invention]The main purposes of this invention are to provide the extracorporeal circulation equipment [operation is easy and] which can also automate operation. moreover -- low -- it is the important purpose that realizing the extracorporeal circulation equipment which makes invasion extracorporeal circulation possible also accompanies. The issue which this invention tends to solve is explained in full detail below.

[0007]Conventionally [<laborsaving and easy-operationality>], when extracorporeal circulation was required in the heart and a large artery operation, the staff for operating extracorporeal circulation was required. And operation of extracorporeal circulation equipment requires the technology in which operation is complicated and advanced, and needs to be experienced. Therefore, this invention controls operation mechanically, its operation is easy and simple and an object of this invention is to provide the equipment which can be saved labor.

[0008]As side effects which <low invasiveness> extracorporeal circulation gives to a living body, inducement of dilution of blood, bleeding by a lot of anticoagulant administration, hemolysis by hematocrasia, or inflammation, the fall of the organ blood flow by an unphysiologic steady flow, etc. are mentioned. In order to decrease these side effects, the extracorporeal circulation equipment which can realize low invasiveness is desirable. On the other hand, since the blood removal pipe used by MICS etc. is thin, the suitable amount of blood removal may not be obtained. Therefore, an object of this invention is to provide the equipment which can secure the blood flow rate which flows through a circulation system, although low invasiveness is secured.
[0009]<Safety> Since conventional extracorporeal circulation equipment is not fully equipped with the security apparatus, it depends for safety on the skill of the engineer who mainly operates extracorporeal circulation. Therefore, an object of this invention is to provide a hardware target or the equipment provided with the security apparatus by software.
[0010]The extracorporeal circulation equipment of the <secured of miniaturization and portability> former is large-sized, and needs to secure a large space. Movement is difficult and it has interfered with elastic employment of equipment. Therefore, this invention aims at a miniaturization and a mobile improvement of a circulation system.
[0011]
[Means for solving problem]In order to solve above-mentioned SUBJECT, the extracorporeal circulation equipment of this invention is provided with the following.
It is the extracorporeal circulation equipment constituted so that a predetermined element might be arranged and extracorporeal circulation of the blood might be carried out into a circuit, and is a blood pump.
The blood reservoir which has a capacity detection means for detecting the capacity regulation means and capacity for fluctuating the capacity to store actively.
The control means for controlling the flow of a blood pump, while the output of a capacity detection means is supplied and controlling the capacity of a blood reservoir via a capacity regulation means.
It is constituted so that it may be possible to control a capacity regulation means by a control means at least, and to adjust the circulation state in a circuit by it. According to this composition, according to being able for a blood reservoir to have a capacity regulation means and a capacity detection means, and to control that capacity, operation of equipment does not need an operator's advanced technology, but will become easy and simple.
[0012]It has preferably a circulation state detection means which detects the circulation state in a circuit, and according to the output which the circulation state detection means detected, a control means constitutes so that the circulation state in a circuit may be adjusted. Thereby, automatic operation becomes easy.

[0013]Let a blood pump be a non-positive-displacement-design blood pump preferably. a blood removal pipe sticks fast by using a non-positive-displacement-design blood pump -- etc. -- can prevent negative pressure excessive at the time of a trouble from occurring, and safety increases, and small -- low -- it is possible to build an invasion system.
[0014]The blood chamber which stores blood for a blood reservoir, and its blood chamber are preferably considered as the composition which has **** external housing. Or the blood chamber which stores blood, the pressure control chambers which adjust the blood volume in the blood chamber adjoined and provided in the blood chamber, and these two rooms are considered as the composition which has **** external housing. In any case, a blood chamber makes it the complete rebreathing system with which the indoor blood does not meet with the open air. By making a blood reservoir into a complete rebreathing system, compulsive blood removal becomes easy from a viewpoint of safety compared with an open sand mold. Therefore, it is also easy to secure a large flow rate and to realize low invasiveness. It becomes easy [a miniaturization]. By changing at least some outer walls of a blood chamber, a capacity regulation means is constituted so that capacity may be adjusted.
[0015]As for a capacity detection means, in these composition, it is preferred to constitute so that the blood volume of a blood chamber may be detected based on the deformed state of the outer wall of a blood chamber. Thereby, regulation of capacity and Measurement Division of capacity can be performed with easy composition. It is preferred to form at least a part of blood chamber with the diaphragm which is a flexible septum. While being able to perform capacity regulation and capacity detection with composition easily by pressing or towing a diaphragm with a gas or a liquid according to this composition, the form of a blood reservoir and the flexibility of a setting position are high. As for a capacity regulation means, when it has a pusher plate which consists of a hard board and the pusher plate presses or tows a septum, it is preferred to constitute so that the capacity of a blood chamber may be adjusted. Thereby, the mechanism for capacity regulation can be simplified and equipment can be manufactured inexpensive.
[0016]A non-positive displacement type pump installs in a circuit preferably only at the upstream of a blood reservoir. According to this composition, it is easy, and the compulsive blood removal by negative pressure can make a blood removal pipe thin, and is advantageous to realization of low invasiveness.
[0017]It constitutes from a pressure sensor in which the circulation state detection means was provided by the inflow part preferably. It constitutes so that a circulation state detection means may detect a circulation state based on the output of the consumed electric current and/or the power consumption monitor which were connected to the drive of a blood pump. A circulation state detection means has preferably a circulation state estimation means to presume a living body's arterial pressure and/or extracorporeal circulation blood flow rate, based on the data

obtained from the inside of a circuit. According to these composition, excessive negative pressure can be prevented from starting a blood removal pipe, a possibility of drawing air decreases, and safety increases. In composition of detecting a circulation state from the consumed electric current of a blood pump, etc., since a sensor is not needed, a system can be manufactured inexpensive.

[0018]Preferably, a control means is controlled to lower the number of rotations of a blood pump, or to lower the capacity of a blood reservoir, when a blood removal part inhales based on the information acquired from a circulation state detection means, **** is detected and it is detected with this ****. It can be coped with easily for a blood removal part sticking fast by that cause, and inhales, **** can be prevented, and safety increases.

[0019]Having a means to set up the preset value which shows the range which serves as a critical value or a target preferably about the information acquired from a circulation state detection means, a control means is based on comparison of the information concerned and preset value, and increases or decreases the extracorporeal circulation flow of blood. Preferably, at least by one side of the operation which raises the number of rotations of a blood pump, or lowers the capacity of a blood reservoir, perform the increase in an extracorporeal circulation flow and reduction of an extracorporeal circulation flow, It constitutes so that at least one side of the operation which lowers the number of rotations of a pump or raises the capacity of a blood reservoir may perform. Thereby, automatic operation of extracorporeal circulation becomes easy.

[0020]It has a means to make a circulation system generate pulsatile flow, by making the number of rotations of a blood pump fluctuate periodically, or making the capacity of a blood reservoir fluctuate periodically preferably. Thereby, suitable organ perfusion is obtained also in the patient who has complication, such as cerebrovascular disease and renal failure.

[0021]Preferably, among the elements arranged in a circuit, at least, a blood pump, a blood reservoir, an artificial lung, and a filter are assembled in one, and are constituted. Thereby, portability increases.

[0022]It has an aeration detection means to detect preferably the aeration arranged at the inflow part of a circuit, and a means to perform at least one side among generating of an alarm, and automatic stay of a pump when it operates according to the output of an aeration detection means and mixing of the air into a circuit is detected. Thereby, the serious trouble of mixing in a circuit of air can be prevented, and safety increases.

[0023]

[Mode for carrying out the invention]Hereafter, with reference to Drawings, an outline is indicated about an embodiment of the invention. The extracorporeal circulation equipment in one embodiment of this invention is shown in drawing 1. Although the same number was attached about the same component as the conventional example of drawing 8, the

arrangement is not necessarily the same as that of a conventional example.

[0024]All over the circuit from the blood removal pipe 2 to the blood transfusion pipe 10, the filter 9, the main pump 6, the artificial lung 7, and the blood reservoir 3 are arranged as main elements toward the lower stream from the upper stream (blood removal tubeside), and they are connected by the short tube one by one. The drive 38a and the motor for driving 38b are formed in the blood reservoir 3 and the main pump 6, respectively. The circuit internal pressure measurement port 37 which contains a ** sensor in the inflow part (the inflow part said by this invention refers to some blood circuits of the upstream from a main pump) of a circuit, and the ultrasonic flowmeter probe 31 are arranged. 39 is a controller which makes a control means and is connected with the blood reservoir 3, the main pump 6, the circuit internal pressure measurement port 37, and the ultrasonic flowmeter probe 31 by the wiring 40. 11 shows the flow of the blood in a circuit.

[0025]The blood reservoir 3 has a capacity regulation means for fluctuating the capacity to store actively. The drive 38a makes a part of element of a capacity regulation means. Although not illustrated by drawing 1, the blood reservoir 3 has a capacity detection means for detecting capacity. The circuit internal pressure measurement port 37 and the ultrasonic flowmeter probe 31 are the means for detecting the circulation state in a circuit.

[0026]The controller 39 controls the capacity and the main pump 6 of the blood reservoir 3 according to the output of the circuit internal pressure measurement port 37 and the ultrasonic flowmeter probe 31. Since the controller 39 holds the reference value for control and performs control based on it, it has a set part for setting up a reference value. Although it is desirable that it is variable as for setting out of a reference value, it may be immobilization depending on the conditions of use. It is not indispensable that control by the controller 39 is automatically performed with the output of the circuit internal pressure measurement port 37 and the ultrasonic flowmeter probe 31. Even if it is the composition of operating the controller 39 manually, when the blood reservoir 3 has a capacity regulation means, it is because the main part of the effect of this invention is obtained. The main things of the above elements are explained in full detail below.

[0027]The blood reservoir 3 and the <capacity adjustment> blood reservoir 3 are provided with the following.

The blood chamber 16 which puts in and collects blood as shown in drawing 2.

The pressure control chamber 17 for adjusting the inner capacity of the blood chamber 16. Both ** 16 and 17 are divided by the existing flexible septum (diaphragm) 18. A communication trunk for 3a and 3b to connect with a circuit and 3c are the communication trunks for connecting the pressure control chamber 17 and a capacity adjustment (not shown). Although not illustrated to drawing 2, it has a capacity detection means which detects the stored blood volume. The blood reservoir 3 can adjust the amount of blood storage actively with a capacity

adjustment. The thing of various forms can be used as the blood reservoir 3 in this invention, and its capacity adjustment. It explains classifying them.

[0028]The blood reservoir generally built into an extracorporeal circulation circuit has an open sand mold with which air touches blood, and an enclosed type which does not touch air. In conventional extracorporeal circulation equipment, the open sand mold reservoir is incorporated in many cases. However, in order to consider it as simple extracorporeal circulation equipment, the reservoir of the open sand mold which must always supervise the amount of blood storage of a reservoir is unsuitable. Therefore, in this invention, an enclosed type is preferred. The blood volume of a blood chamber is made to fluctuate actively, and there are a hydrostatic pressure type which adjusts blood volume, and a mechanical cable type which adjusts blood volume second by [direct] carrying out pressure towage of the blood chamber mechanically by carrying out pressure towage of the blood chamber via the first liquid or gas as a capacity adjustment for adjusting.

[0029]In the first hydrostatic pressure type, as shown in drawing 2, two rooms, the blood chamber 16 which puts in blood, and the pressure control chamber 17 which wrap in the whole or a part of blood chamber and into which the gas and liquid for ****** are put, exist. The whole or some of container serves as elasticity, ** of the pressure control chamber 17 is reflected in the blood chamber 16 via the elasticity portion of the blood chamber 16, and, as for the blood chamber 16, the capacity of the blood chamber 16 is adjusted. Drawing 2 shows the blood reservoir which has the existing flexible septum (diaphragm) 18 also in a hydrostatic pressure type.

[0030]A gas or a liquid may be sufficient as the medium of **. If the liquid had mobility, it is [anything] good. Although the degassing physiological saline from which it sterilized and dissolved gas was removed is preferred, the mere water which has not sterilized since blood is not touched directly may be sufficient. Fluids, such as a liquid and a gas, are sent into a pressure control chamber, and the blood reservoir capacity adjustment made to generate suitable ** may be separately installed via a tube, although including in a blood chamber is also possible. The whole system becomes compact when it incorporates. When it is made separate, the blood chamber itself becomes compact and its restriction of the setting position of a blood chamber decreases.

[0031]A blood reservoir capacity adjustment is [anything which may generate suitable **] good. When a medium is air, it is also possible to use the compressor which can adjust **. When a medium is a liquid, there are a system (capacity regulation system) which specifies capacity, such as a syringe and bellows, directly, and a system (pump fluid pressure control mode) which adjusts fluid pressure using a liquid-sending pump.

[0032]The equipment of structure as shown in drawing 3 can be used for a capacity regulation system. The figure (a) shows the equipment which specifies the capacity of a pressure control

chamber using the piston 19. The pressure adjusted by the position of the piston 19 is transmitted to the pressure control chamber 17 via the communication trunk 19a. As for the Drawing (b), (c), and (d), capacity is respectively adjusted with the syringe 20, the bellows 21, and the pusher plate 22. It is respectively connected to the pressure control chamber 17 via the communication trunks 20a, 21a, and 22a like (a). The piston 19, the syringe 20, the bellows 21, and the pusher plate 22 are driven by a motor etc.

[0033]In a pump fluid pressure control mode, the capacity of a pressure control chamber is adjusted using the liquid-sending pump for blood reservoir capacity adjustments. The pump used here is [anything] applicable if liquid sending is possible. As performance called for, it is small and what is excellent in reliability and endurance, is excellent in a response, and can generate high ** regardless of the direction of liquid sending, and cost does not require is good. Specifically, a centrifugal pump, a mixed flow pump, a propeller pump, a friction pump, a gear pump, a roller pump, etc. are mentioned. The switching valve into which a centrifugal pump and a mixed flow pump change a direction since the direction of liquid sending is one way is needed. Drawing 4 (a) and (b) shows the example which used the roller pump 23 and the propeller pump 24, respectively. In a figure, 25 is a liquid-storage room for liquid sending.

[0034]As the second mechanical cable type, composition as shown in drawing 5 can be used. In this case, a blood reservoir capacity adjustment becomes the structure coupled directly with the blood chamber. Drawing 5 (a) is the example which used the piston 12. The blood chamber 12c serves as a container variable in capacity by the position of the piston 12. 12a and 12b are the communication trunks for connecting with a circuit. The Drawing (b), (c), and (d) shows respectively the example in which capacity is adjusted with the syringe 13, the bellows 14, and the pusher plate 15. As a driving source, a motor, an electromagnet, etc. are used and capacity is adjusted by receiving a certain pressure towage.

[0035]In both the first mechanical cable type and the second hydrostatic pressure type, form of a blood chamber must be made into what has a few blood-flow **** part in order to improve anti-thrombus nature. It is thought that the direction of a hydrostatic pressure type has little restriction of the design of a blood chamber, and is superior to a mechanical cable type in anti-thrombus nature. On the other hand, since a mechanism is simple, and part mark also have them and it ends, a mechanical cable type can be manufactured inexpensive. [few] Although the target patient calls on an adult or a child, if the region of accommodation of blood chamber capacity is an adult, it is desirable for it to be able to adjust to 100 ml - 4000 ml.

[0036]The thing of various forms can be used as composition of the capacity detection means which detects the capacity of a blood chamber. If a piston, a syringe, and bellows are used for a blood chamber, capacity is simply detectable with the displacement position of the axis of rotation of a drive motor. The capacity of a blood chamber is measurable also by the method of attaching capacity detection means, such as a hall sensor and an ultrasonic crystal, to a blood

chamber or a pressure control chamber, or sending weak current through a blood chamber and measuring impedance and conductance with a current potential plan. When the fluid is liquid in the case of a hydrostatic pressure type, even if it measures the capacity of the liquid discharged via the tube from the regulating chamber with a volume plan, the capacity of a blood chamber can be measured. Since the mensuration of the capacity of the discharged liquid has high flexibility, it can consider many methods, but it is good to measure weight with a weigher simply. The means for supplying detected information is required for the controller 39, and for that purpose, it constitutes so that a detection result may be outputted as an electrical signal, for example.

[0037]It is possible to include a heat exchanger in the blood reservoir in this invention. There are some methods incorporating a heat exchanger and the following is mentioned as an example. Warming of a living body and cooling are possible for blood ****** by installing the tube made with the construction material which was excellent in heat exchange ability in the blood chamber of a blood reservoir in the first place, and carrying out perfusion of the liquid warmed or cooled in the tube. Warming of a living body and cooling are possible for blood ****** by warming or cooling a pusher plate in the mechanical reservoir which used the pusher plate for the second. If it limits only to warming, how to build a heater into a pusher plate will also be considered, and it will be a simple and effective method. Warming of a living body and cooling are possible for blood ****** by warming or cooling the liquid in a pressure control chamber with a hydraulic system reservoir to the third. It is an effective method, also in order to lose the **** part of blood, to think that anti-thrombus nature becomes high and to improve low invasiveness rather than installing a heat exchanger in a blood chamber.

[0038]The <main pump 6>, next the main pump 6 are explained. Since the blood removal pipe used by MICS etc. is thin, the suitable amount of blood removal may not be obtained. Therefore, it is necessary to add the suitable negative pressure which is not excessive to blood removal. Since addition negative pressure has a limit in fall blood removal, the compulsive blood removal using a pump is preferred. In fall blood removal, in order to enlarge a fall, it is necessary to make an operating table high but, and in compulsive blood removal, the same operating table as the general operation of those other than the heart can be used, and it is effective on employment of an operating room.

[0039]Generally, there are a positive-displacement design and a non-positive-displacement design in a liquid-sending pump. The roller pump mostly used to extracorporeal circulation equipment is classified into a positive displacement pump. the problem at the time of using a positive displacement pump for the main pump of extracorporeal circulation equipment, and moreover installing in the upper stream from a blood reservoir sticks to a blood removal pipe -- etc. -- when the obstacle of a circuit arises, it is that excessive negative pressure occurs in the inflow part of a pump. Excessive negative pressure may damage the body tissue of a blood

removal part, and may cause serious troubles, such as drawing in into the circuit of air. for this reason -- sticking fast as a kind of main pump installed in the upper stream from a blood reservoir -- etc. -- the non-positive displacement type pump which excessive negative pressure did not occur at even if it produced, but was excellent in accommodativeness is preferred. The typical things of a non-positive displacement type pump are turbo-pumps, such as a centrifugal pump, a mixed flow pump, and a propeller pump. Although these all can be used for this invention, since the propeller pump needs to make number of rotations very high in order to generate high **, if hemolysis and endurance are taken into consideration, it is not desirable selection. Therefore, a centrifugal pump and a mixed flow pump are preferred.

[0040]Control of a circulation state by the controller 39 in <the controller 39 and a circulation state detection means>, next the extracorporeal circulation equipment of this invention is explained. In order to make operation of extracorporeal circulation equipment simple and to Automatic Control Division-ize it most preferably, control by a computer is required. It is also effective in control to consider and combine some methods.

[0041]the 1st method is based on ** -- it sticks fast and they are detection and prevention. That is, if monitor the inlet pressure of a circuit, it inhales from a pressure wave form, **** is detected and inhaled and **** appears, control which lowers the number of rotations of a pump or lowers the capacity of a blood reservoir will be performed. Reflecting venous pressure, if ** of an inflow part is normal, it serves as a steady flow which does not almost have pulse pressure. However, if a blood removal pipe sucks up and **** arises, disorder of the unusual pressure wave form characterized by the rapid fall of ** will arise. This serves as increase of pulse pressure, increase of a pressure change (increase of the absolute value of ********), and change of **********, and appears. The ** sensor of the pressure measuring port 37 which constitutes a circulation state detection means detects this, and the information acquired by it is transmitted to the controller 39 which is a control means. The computer is built into the controller 39, and using the information acquired from the ** sensor, the main pump 6 and/or a blood reservoir are adjusted so that blood may flow through the inside of extracorporeal circulation equipment favorably.

[0042]If the 2nd method sets up the lower limit value of inlet pressure and it is less than a preset value, it will be the controlling method which lowers the number of rotations of a pump or lowers the capacity of a blood reservoir. Although a certain amount of [a lower limit value] negative pressure is unavoidable, since it becomes the origin of obstacles, such as cavitation generating of a main pump and drawing in into the circuit of unexpected air, negative pressure which is less than -100mmHg must be prevented. In order to measure the inlet pressure of a circuit as a circulation state detection means like the 1st method also in this case, the ** sensor 37 shown in drawing 1 is used. It is required for the controller 39 to have a means to set up the lower limit value of inlet pressure.

[0043]The 3rd method will be the controlling method which lowers the number of rotations of a pump or lowers the capacity of a blood reservoir, if measure the consumed electric current or electric power of a blood pump, a blood removal part inhales from the waveform of the consumed electric current or electric power, **** is detected and inhaled and **** appears. Although this is fundamentally the same as the 1st method, in order to use the in-house data which the motor of a pump has, a special sensor is not needed, but it leads to reduction of cost. In this case, since the consumed electric current and power consumption of a drive (motor) which are driving the blood pump must be measured, a means to monitor the current or electric power of a motor of a pump is needed as a circulation state detection means.
[0044]If a living body's arterial pressure and extracorporeal circulation blood flow rate used as a target are set up and both this arterial pressure, this flow, or either is less than a preset value, the 4th method, If pump rotation frequency is raised, or the capacity of a blood reservoir is lowered and both this arterial pressure and this flow exceed a preset value, it will be the controlling method which lowers pump rotation frequency or raises the capacity of a blood reservoir. The arterial pressure and the extracorporeal circulation blood flow rate to set up must be determined according to a living body's individual difference or the condition of the technique and a living body, and cannot consider setting it as the same value in any situations. However, it is possible to decide target arterial pressure suitable for each case and an extracorporeal circulation blood flow rate to be beforehand, and it is not necessary to change a preset value frequently during extracorporeal circulation implementation. It is not especially limited which shall be given priority to and adjusted between pump rotation frequency and blood reservoir capacity, but it is both possible.
[0045]Until it sets up the optimum upper limit (it is described as Arpm) of pump rotation frequency and exceeds Arpm as one desirable method, It controls towards giving priority to blood reservoir capacity, increasing capacity, and considering it as the maximum (full blood removal), and if it will be necessary to exceed Arpm in order to make a blood flow rate increase, how to reduce blood reservoir capacity without raising number of rotations can be considered. Administration of a pressure-up agent or vasodepressor is also required during extracorporeal circulation, and suitable treatment is needed suitably. If a living body's arterial pressure and extracorporeal circulation blood flow rate are measurable as a circulation state detection means provided in extracorporeal circulation equipment in the case of the 4th method, a pressure (blood) monitor line, a blood flow merer, etc. which it was not limited in particular, for example, were formed in blood circuits will be mentioned.
[0046]Reduction of the fill ration of an extracorporeal circulation circuit is attained by simplifying a <simplification of circuit and system> circuit and shortening a tube as much as possible. The reduction in a fill ration can be contributed to low invasiveness by suppressing generating of the edema by the hemodilution and reducing the necessity for blood transfusion

substantially. By assembling the circuit on the manufacture level beforehand, a labor required for an assembly is omitted and it is connected with human laborsaving and cost reduction. If the restoration in a circuit is also substituted for the manufacture level, preparation further before an operation is mitigable. Conventional extracorporeal circulation equipment is large-sized, and the large space needed to be secured, and since movement was difficult, it had interfered with elastic employment of equipment. In this invention, a circuit and a drive are designed compactly, it is possible to secure portability and these problems are also solved.

[0047]In the patient who has complication, such as <pulsation and oscillating additional-equipment> cerebrovascular disease and renal failure, the validity of the extracorporeal circulation which has pulsatile flow is accepted. Therefore, also in this invention, it is effective to enable addition of pulsation and vibration, also in order to attain low invasion-ization. The following can be considered to the method of adding pulsation and vibration. It is the method of generating pulsatile flow, by making the number of rotations of a pump 1st fluctuate periodically. It is the method of generating pulsatile flow thru/or vibration, by making the 2nd fluctuate the capacity of a blood reservoir periodically. Especially the latter is the new method which employed efficiently the feature of the blood reservoir that capacity could be adjusted actively. It is also possible to use the 1st and the 2nd method together, and it is effective.

[0048]Antithrombotic processing is performed to the blood contacting surface of a <anti-thrombus processing> circuit. In this invention, it is a complete rebreathing system which does not touch air, and in order to use the blood reservoir which improved anti-thrombus nature with few blood-flow **** parts, antithrombotic processing and the extracorporeal circulation in conjointly more few anticoagulants become possible. By the usual extracorporeal circulation, anticoagulants, such as heparin, are prescribed for the patient and, specifically, operation of the place which keeps activated coagulation time at 400 seconds or more is enabled in 250 seconds from 200 seconds. As a result, bleeding decreases, and shortening of operation time, the fall of the necessity for blood transfusion, etc. are effective in order to improve the low invasiveness of extracorporeal circulation equipment.

[0049]As an example is shown in <separation type navigational panel> drawing 6, the separation type navigational panel 26 which can be installed in a field of operation is used, and operation required for control presupposes that it is possible from a field of operation. The necessity that this provides a special extracorporeal circulation operator decreases, and it leads to human laborsaving. The separation type navigational panel can consider what hung the transparent sterilization covering 27 on the touch-sensitive liquid crystal display. while it installs in the place which the way person's 28 (or the first assistant) hand reaches and the surveillance and control of extracorporeal circulation perform an operation using a sound or a sound -- **** -- a user interface which becomes possible is preferred.

[0050]Operation of <remote control function> extracorporeal circulation will serve as

surveillance from remoteness controllable from hand control, if it automates more. If a concrete example is shown, data required for the surveillance and control of extracorporeal circulation will be put on a network by the standards (for example, combination of GPIB and TCP/IP, etc.) of a flexible measuring instrument and communication, and batch management will be carried out at an extracorporeal circulation central control room. Many pieces of extracorporeal circulation equipment is the effective methods of leading to human laborsaving in the large-scale hospital currently operated simultaneously. Since it becomes possible to record and save all the data, it is useful for scientific practical use.

[0051]An aeration into a <aeration arrester in circuit> circuit is one of the serious troubles which arise during extracorporeal circulation operation. I hear that that it is a simple system has so high safety that it can be used simple, and there is. Some methods can be considered in the ways of coping to an aeration. A bubble detection function is given to the flow instrument the 1st, using an ultrasonic flowmeter as a flow instrument which monitors an extracorporeal circulation blood flow rate. If the probe 31 of an ultrasonic flowmeter is attached to the inflow part of a circuit and a bubble is detected as shown in drawing 1, an alarm will be emitted promptly and it will be coped with.

[0052]The filter 32 is installed in a circuit inflow part the 2nd. The filter 32 is installed in the highest place of a circuit, and it is made for air to accumulate. If the optical sensor 33 for detecting air for an example in the filter 32 as shown in drawing 7 is installed and air accumulates [3rd], this will be detected, an alarm will be emitted promptly and a pump will be stopped. The port 34 for discharging air is installed in the upper tip of the filter 32, and the port 34 is connected [4th] to the suction circuit 35. Usually, this port 34 is intercepted by the breaker 36. If the filter 32 is covered with air, interception of a port will be canceled hand control or automatically promptly, and suction discharging of the air will be carried out outside. It is possible to combine the plurality of these methods or all, and it is effective. 30 in drawing 7 shows the flow of blood.

[0053]Some peripheral equipment is needed for <linkage with peripheral equipment> extracorporeal circulation equipment by the technique. That is, they are the reservoir for a suction circuit and suction circuits, hemoconcentration equipment (cell SEBA, ultrafiltration equipment), a myocardium protection liquid circuit and an injector, a vent circuit, etc. In this invention, it is effective to aim at linkage with these pieces of equipment.

[0054](Concrete embodiment) The more concrete embodiment which was suitable for below at it as an example of an operation which uses the extracorporeal circulation equipment of this invention on the assumption that the mitral valve operation under MICS is described.

[0055]As shown in drawing 1 toward the lower stream (blood transfusion tubeside) from the upper stream (blood removal tubeside) of a <composition of extracorporeal circulation equipment> circuit, the filter 9, the pump 6, the artificial lung 7, and the blood reservoir 3 are

connected by a short tube one by one. These are compact and what has the few amount of filling liquid is preferred. If these are already assembled at the time of shipment, they are convenient. These are preferred, a compact thing and installing in the sterilization field of operation of an operation conjointly can also be sterilized and supplied, and it is effective. If it can install in a sterilization field of operation, the tube for connecting with a blood removal pipe or a blood transfusion pipe can be shortened further, and the whole amount of filling liquid can be lessened further. Capture and interception of the air which mixed the filter in the circuit with removal of the impurity are the purposes. In order to capture air, it installs in the highest position in all the circuits.

[0056]Although its turbo-pump is preferred, if a pump is a small mixed flow pump, it is still more preferred. If sterilization with waterproofness is possible for the motor for driving a pump, it can be installed in a sterilization field of operation, and its handling is convenient. Or handling is still more convenient if it has sterilized by the same product made from disposal as a pump. A compact thing is preferred although anythings can use an artificial lung. Especially the thing that was excellent in gas exchange ability or haemocompatibility is preferred, and its membrane type is better than this point to an air-bubbles type. A blood reservoir measures mechanically the blood volume by which blood storage was carried out, and makes it what can be adjusted. Although various modes can be considered, an example is given about each of a mechanical cable type and a hydraulic system.

[0057]A mechanical cable type uses a pusher plate. The blood chamber of a blood reservoir consists of hard housing and a flexible film. A blood reservoir drive serves as a motor for pressing and towing the hard pusher plate and pusher plate for pressing the flexible film of a blood chamber from a motor controller. The pusher plate must be what can press the flexible film of a blood reservoir uniformly. The load concerning a pusher plate becomes uniform and the direction in which the blood reservoir was installed so that a pusher plate might become level to a floor is preferred. It will warm, if it will be necessary to embed a heater and to raise a patient's body temperature into a PUSHA plate. Although the motor must have a means to change rotation into a straight-line motion, the linear motor which produces a straight-line motion from the start may be used. A motor controller mainly performs position control of a motor. Capacity Measurement Division of a blood chamber is performed by detecting the position of a motor.

[0058]In a fluid pressure type, a flexible septum (diaphragm) is put on the inside of a transparent hard plastic container, and two cavities, a blood chamber and a pressure control chamber, are provided. The pressure control chamber is connected to the liquid-storage room for liquid sending by the connection tube. The pressure control chamber, the liquid-storage room, and the connection tube are filled with the liquid for liquid sending (tap water is used). The roller pump is installed in the middle of the connection tube, by making for Masakata or an

opposite direction rotate a roller pump, the capacity of a pressure control chamber is adjusted and, as a result, the capacity of a blood chamber is adjusted. By a fluid pressure formula, what kind of angle may be sufficient as installation of a blood reservoir to a floor, and its flexibility of installation is high. It will warm, if it will be necessary to embed a heater and to raise a patient's body temperature into a pressure control chamber. As shown in drawing 1, the circuit internal pressure measurement port 37 is established in an inflow part, and inflow part circuit internal pressure is monitored. An ultrasonic flowmeter (with bubble detection function) probe is attached to an inflow part.

[0059]The function to make extracorporeal circulation equipment generate pulsatile flow is added. Powerful pulsation addition capability is obtained by taking a synchronization periodically and changing the number of rotations of the motor of a pump, and the capacity of a blood reservoir. Different consideration from conventional extracorporeal circulation equipment is required for the connection order foreword of extracorporeal circulation equipment each component of this invention. Since capture and interception of the air mixed in the circuit are the big purposes, a filter is installed in the style of Mogami. In negative pressure and the lower stream, the upper stream serves as positive pressure from the pump. Therefore, an artificial lung is put on the positive pressure side. If a blood reservoir is the above-mentioned mechanical cable type, it is more desirable to install it in the positive pressure side, although it can install in both negative pressure and positive pressure. If the inside of a blood chamber is positive pressure, it becomes unnecessary for the Reason to carry out forcible towage of the pusher plate, and to carry out adhesion fixing of between the flexible film of a blood reservoir, and pusher plates, and it is assembly top convenience. In order to generate pulsatile flow using a blood reservoir, it is desirable to install a blood reservoir downstream most. As mentioned above, it is desirable to become the order of a filter, a pump, an artificial lung, and a blood reservoir from the upper stream (blood removal tubeside) of a circuit toward the lower stream (blood transfusion tubeside).

[0060]There are many functions required for the controller for driving and controlling extracorporeal circulation equipment. In this function, it controls with rotation of a pump motor, and control and the drive of a blood reservoir drive motor at least, External data inputs, such as communication with the transducer for inflow part circuit internal pressure measurement, and amplifier, an ultrasonic flowmeter (with a bubble detection function) and a separation type navigational panel and a patient's blood pressure, control of the whole system, etc. are included. An interlocking function with the reservoir for a suction circuit and suction circuits, hemoconcentration equipment (cell SEBA, ultrafiltration equipment), a myocardium protection liquid circuit and an injector, a vent circuit, etc. is also effective. The input output function of the surveillance and control data through a network is also effective. In order to improve space-saving [of a system], and portability, the small and movable thing of the controller is preferred.

[0061]The filter, the pump, artificial lung, and blood reservoir which constitute the extracorporeal circulation equipment of <setting of operation> this invention can be installed in a sterilization field of operation by assembling at the time of shipment and making sterilization complete in a short time. Before installing the restoration in a circuit, and air extraction in a sterilization field of operation, they are possible also later. If the silicon film production type lung which a liquid break through does not generate is used, it will be possible to also make it already complete to restoration at the time of shipment, and it will lead to large laborsaving. The port for air extraction is established in the filter and the blood reservoir. An extracorporeal circulation equipment controller is installed near the operating table. Inflow part circuit internal pressure is monitored and the sterilized ultrasonic flowmeter (with bubble detection function) probe is attached. A suction circuit, a myocardium protection liquid circuit, etc. are prepared. Transparent sterilization covering is covered over a separation type navigational panel, and it installs in the place which a way person tends to operate. Extracorporeal circulation is operated under cooperation of a way person, an operation assistant, and an anesthesiologist. Therefore, the special staff only for extracorporeal circulation device operation is not stationed.

[0062]The procedure of the mitral valve operation under MICS using the extracorporeal circulation equipment of <implementation of operation> this invention is mentioned as an example. Skin incision is shortened as much as possible, the partial median sternotomy is performed, and the heart is exposed. Small incision is added to a right inguinal region, and a femoral artery and vein is exposed. A blood transfusion pipe is inserted in a femoral artery, and a blood removal pipe is inserted in an inferior vena cava from a femoral vein. A blood removal pipe is directly inserted in superior vena cava from a sternotomy part. The double snare on a tape is hung on the right-atrium close relationship of superior vena cava and an inferior vena cava, and it is considered as tourniquet. Interception of this tourniquet must fully be possible so that the compulsive blood removal by the negative pressure of a vein may not draw air, either. Although the thickness of a blood removal pipe changes with patients, insertion is also simple for a thin thing and it does not become the hindrance of a view. KANYURA for myocardium protection liquid pouring is installed in an ascending aorta. It fills up and the extracorporeal circulation circuit which air extraction ended, and the blood transfusion pipe and blood removal pipe which were attached to the patient are connected. It checks that there is no problem in the whole circuit, and extracorporeal circulation is started.
[0063]Extracorporeal circulation makes automatic operation possible fundamentally. On condition that it is not less than the value which patient arterial pressure set up beforehand, pump rotation frequency is raised until a set flow rate is obtained. If a set flow rate is obtained, the capacity of a blood reservoir will be raised next. As long as patient arterial pressure and a

flow allow, the capacity of the blood reservoir is raised. It checks that stable extracorporeal circulation operation is obtained, an ascending aorta is intercepted, myocardium protection liquid is poured in, and the heart is stopped. Myocardium protection liquid, bleeding, etc. which have carried out perfusion are attracted, and are brought together in the reservoir for suction circuits. The collected liquid is processed with hemoconcentration equipment (cell SEBA, a ultrafiltration equipment, etc.), and is transfused into a patient. Since operation of hemoconcentration equipment is easy, even if it is not the extracorporeal circulation engineer trained specially, it can be enforced.

[0064]Up-and-down vena cava are intercepted and it results in a mitral valve by the right atrium and the atrioseptostomy, or left-atrium incision. Even if the method of a mitral valve operation, for example, mitral valve replacement, and mitral annuloplasty is MICS, it is not different from usual. The air after the end of treatment of a mitral valve and in the heart is removed enough, ascending aorta interception is canceled, and suture closing of the cardiotomy part is carried out thoroughly. Up-and-down vena-cava interception is canceled, an extracorporeal circulation flow is lowered, and extracorporeal circulation will be ended if the heart beat is enough. Since it is required to carry out manually to some extent and ** is after the end of mind operation, a way person and an operation assistant can enforce the separating operation from extracorporeal circulation.

[0065]The serious trouble under <safety measures to aeration> extracorporeal circulation enforcement has the aeration in a circuit. Especially when the blood reservoir of an enclosed type is used, since there is a danger of sending into a patient's artery if air is not removed promptly, it is a problem. The mixing part of air is an upstream negative pressure side from a pump. Therefore, it is important not to establish an unnecessary port in the negative pressure side. The terminal area of a circuit also needs a device from which it does not separate simply. Even if satisfactory in the circuit itself, air may be drawn in a blood removal pipe from the inside of the heart. Therefore, interception of up-and-down vena cava must be made into a positive thing.

[0066]A pump is controlled and inhaled and **** is prevented so that it may not become negative pressure with excessive inflow part circuit internal pressure. Even if it performs these safety measures, in consideration of a possibility that air will mix, a security apparatus is established further. The mixed air is detected by the bubble detection function of an ultrasonic flowmeter, sounds an alarm promptly, lowers the number of rotations of a pump, and reduces a flow. However, a stop is not carried out. Since a stop of a pump means circulation interception, the easy pump stop cannot say it as suitable correspondence. If the sensor of air detection is attached also to a filter and air accumulates more than fixed, a pump will be stopped promptly. The port of air extraction is established in the upper bed of the filter, a suction circuit is connected beforehand, and it usually intercepts. If air is detected by a bubble

detection function or air accumulates in a filter, by automatic or manual operation, the interception to a suction circuit will be canceled and air will be removed outside a circuit. Also to a blood reservoir, an air extraction port is established in an upper bed, and it escapes from air if needed.

[0067]

[Effect of the Invention]According to this invention, when a blood reservoir has a capacity regulation means and a capacity capacity detection means, control of extracorporeal circulation is easy and the extracorporeal circulation equipment with which the burden of equipment operation was eased can be provided. Automation of equipment operation is also attained. furthermore -- since equipment can be safely operated even if it makes high the amount of driving flow of a blood pump by controlling a blood reservoir and a blood pump collectively -- low -- invasion extracorporeal circulation becomes possible.

[Translation done.]

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TECHNICAL FIELD

[Field of the Invention]this invention was provided with the extracorporeal circulation equipment of blood, and the function which controls a circulation state especially -- simple -- low -- it is related with invasion extracorporeal circulation equipment.

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PRIOR ART

[Description of the Prior Art]In the operation of the heart and a large artery, in order to change the heart temporarily into the state near a stop or a stop and to make the function of the heart and a lung take over with a machine, extracorporeal circulation equipment is used. The extracorporeal circulation equipment currently used conventionally is composition which was provided with the blood removal pipe 2, the blood reservoir 83, the heat exchanger 5, the main pump 86, the artificial lung 7, the filter 9, and the blood transfusion pipe 10, and has arranged those elements one by one all over blood circuits as main elements, as shown in drawing 8.
[0003]The blood removal pipe 2 is inserted in the patient's 1 up-and-down vena cava and right atrium, and in order to take many flows, a thick thing is used as much as possible. As for the blood reservoir 83, many open sand molds with which blood touches air are used.
By fall blood removal which used the fall of the blood reservoir 83 with the patient 1, blood flows through a blood removal pipe.
Although it is a small number, the blood reservoir of the enclosed type with which blood does not touch air is also used, and there are some into which blood flows through a blood removal pipe by compulsive blood removal using a blood pump. In the blood reservoir of an open sand mold, since a risk of sending in air in a circuit will increase if the blood volume which stored liquid falls, there are some which emit an alarm, but what adjusts capacity actively is not known. The heat exchanger 5 is installed in a blood reservoir in many cases, carries out perfusion of the liquid (usually tap water) warmed thru/or cooled by metal tubes with the heating-cooling equipment 4, and warms thru/or cools blood. A roller pump or a centrifugal pump is used and the main pump 86 is installed downstream from the blood reservoir. The example currently installed upstream of the blood reservoir does not have a main pump. The whole extracorporeal circulation equipment is large-sized, and needs to secure a large space compared with a general operation. It is not suitable for carrying for a large-sized machine, and is always installed in the space undergoing an operation.

[0004]Operation of extracorporeal circulation equipment is performed by stationing the special staff for it. Although an extracorporeal circulation engineer takes on the duties, a medical practitioner may usually perform an extracorporeal circulation operator. Anyway, the special staff who acquired advanced technology is required. An extracorporeal circulation operator is located beside an operating table, does not join operation or is never located in a remote place. The extracorporeal circulation operator is performing adjustment of the capacity of a blood reservoir, or a pump flow rate by manual operation in consideration of the optimum extracorporeal circulation blood flow rate, looking at the grade of blood removal, and a living body's arterial pressure. Therefore, an extracorporeal circulation operator cannot separate from extracorporeal circulation equipment during extracorporeal circulation enforcement.
[0005]By the way, in order to utilize a human and economical medical resource effectively, in the surgery field, the no-touch isolation technique is introduced positively. The no-touch isolation technique in a cardiovascular surgery field is called MICS (Minimally Invasive Cardiac Surgery; low invasion heart surgery). In MICS, in order to reduce invasion, median sternotomy covering an overall length is not performed, but skin incision is shortened as much as possible. Therefore, the view for exposing the heart is restricted. Therefore, the thin thing from which the blood removal pipe used for extracorporeal circulation equipment does not become the hindrance of a view is liked.

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EFFECT OF THE INVENTION

[Effect of the Invention]In this invention, a blood reservoir has a capacity regulation means and a capacity capacity detection means.
Therefore, control of extracorporeal circulation is easy and the extracorporeal circulation equipment with which the burden of equipment operation was eased can be provided. Automation of equipment operation is also attained. furthermore -- since equipment can be safely operated even if it makes high the amount of driving flow of a blood pump by controlling a blood reservoir and a blood pump collectively -- low -- invasion extracorporeal circulation becomes possible.

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TECHNICAL PROBLEM

[Problem to be solved by the invention]The main purposes of this invention are to provide the extracorporeal circulation equipment [operation is easy and] which can also automate operation. moreover -- low -- it is the important purpose that realizing the extracorporeal circulation equipment which makes invasion extracorporeal circulation possible also accompanies. The issue which this invention tends to solve is explained in full detail below.
[0007]Conventionally [<laborsaving and easy-operationality>], when extracorporeal circulation was required in the heart and a large artery operation, the staff for operating extracorporeal circulation was required. And operation of extracorporeal circulation equipment requires the technology in which operation is complicated and advanced, and needs to be experienced. Therefore, this invention controls operation mechanically, its operation is easy and simple and an object of this invention is to provide the equipment which can be saved labor.
[0008]As side effects which <low invasiveness> extracorporeal circulation gives to a living body, inducement of dilution of blood, bleeding by a lot of anticoagulant administration, hemolysis by hematocrasia, or inflammation, the fall of the organ blood flow by an unphysiologic steady flow, etc. are mentioned. In order to decrease these side effects, the extracorporeal circulation equipment which can realize low invasiveness is desirable. On the other hand, since the blood removal pipe used by MICS etc. is thin, the suitable amount of blood removal may not be obtained. Therefore, an object of this invention is to provide the equipment which can secure the blood flow rate which flows through a circulation system, although low invasiveness is secured.
[0009]<Safety> Since conventional extracorporeal circulation equipment is not fully equipped with the security apparatus, it depends for safety on the skill of the engineer who mainly operates extracorporeal circulation. Therefore, an object of this invention is to provide a hardware target or the equipment provided with the security apparatus by software.

[0010]The extracorporeal circulation equipment of the <secured of miniaturization and portability> former is large-sized, and needs to secure a large space. Movement is difficult and it has interfered with elastic employment of equipment. Therefore, this invention aims at a miniaturization and a mobile improvement of a circulation system.

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MEANS

[Means for solving problem]In order to solve above-mentioned SUBJECT, the extracorporeal circulation equipment of this invention is provided with the following.
It is the extracorporeal circulation equipment constituted so that a predetermined element might be arranged and extracorporeal circulation of the blood might be carried out into a circuit, and is a blood pump.
The blood reservoir which has a capacity detection means for detecting the capacity regulation means and capacity for fluctuating the capacity to store actively.
The control means for controlling the flow of a blood pump, while the output of a capacity detection means is supplied and controlling the capacity of a blood reservoir via a capacity regulation means.
It is constituted so that it may be possible to control a capacity regulation means by a control means at least, and to adjust the circulation state in a circuit by it. According to this composition, according to being able for a blood reservoir to have a capacity regulation means and a capacity detection means, and to control that capacity, operation of equipment does not need an operator's advanced technology, but will become easy and simple.
[0012]It has preferably a circulation state detection means which detects the circulation state in a circuit, and according to the output which the circulation state detection means detected, a control means constitutes so that the circulation state in a circuit may be adjusted. Thereby, automatic operation becomes easy.
[0013]Let a blood pump be a non-positive-displacement-design blood pump preferably. a blood removal pipe sticks fast by using a non-positive-displacement-design blood pump -- etc. -- can prevent negative pressure excessive at the time of a trouble from occurring, and safety increases, and small -- low -- it is possible to build an invasion system.
[0014]The blood chamber which stores blood for a blood reservoir, and its blood chamber are preferably considered as the composition which has **** external housing. Or the blood

chamber which stores blood, the pressure control chambers which adjust the blood volume in the blood chamber adjoined and provided in the blood chamber, and these two rooms are considered as the composition which has **** external housing. In any case, a blood chamber makes it the complete rebreathing system with which the indoor blood does not meet with the open air. By making a blood reservoir into a complete rebreathing system, compulsive blood removal becomes easy from a viewpoint of safety compared with an open sand mold. Therefore, it is also easy to secure a large flow rate and to realize low invasiveness. It becomes easy [a miniaturization]. By changing at least some outer walls of a blood chamber, a capacity regulation means is constituted so that capacity may be adjusted.

[0015]As for a capacity detection means, in these composition, it is preferred to constitute so that the blood volume of a blood chamber may be detected based on the deformed state of the outer wall of a blood chamber. Thereby, regulation of capacity and Measurement Division of capacity can be performed with easy composition. It is preferred to form at least a part of blood chamber with the diaphragm which is a flexible septum. While being able to perform capacity regulation and capacity detection with composition easily by pressing or towing a diaphragm with a gas or a liquid according to this composition, the form of a blood reservoir and the flexibility of a setting position are high. As for a capacity regulation means, when it has a pusher plate which consists of a hard board and the pusher plate presses or tows a septum, it is preferred to constitute so that the capacity of a blood chamber may be adjusted. Thereby, the mechanism for capacity regulation can be simplified and equipment can be manufactured inexpensive.

[0016]A non-positive displacement type pump installs in a circuit preferably only at the upstream of a blood reservoir. According to this composition, it is easy, and the compulsive blood removal by negative pressure can make a blood removal pipe thin, and is advantageous to realization of low invasiveness.

[0017]It constitutes from a pressure sensor in which the circulation state detection means was provided by the inflow part preferably. It constitutes so that a circulation state detection means may detect a circulation state based on the output of the consumed electric current and/or the power consumption monitor which were connected to the drive of a blood pump. A circulation state detection means has preferably a circulation state estimation means to presume a living body's arterial pressure and/or extracorporeal circulation blood flow rate, based on the data obtained from the inside of a circuit. According to these composition, excessive negative pressure can be prevented from starting a blood removal pipe, a possibility of drawing air decreases, and safety increases. In composition of detecting a circulation state from the consumed electric current of a blood pump, etc., since a sensor is not needed, a system can be manufactured inexpensive.

[0018]Preferably, a control means is controlled to lower the number of rotations of a blood

pump, or to lower the capacity of a blood reservoir, when a blood removal part inhales based on the information acquired from a circulation state detection means, **** is detected and it is detected with this ****. It can be coped with easily for a blood removal part sticking fast by that cause, and inhales, **** can be prevented, and safety increases.

[0019]Having a means to set up a preset value which shows a range which serves as a critical value or a target preferably about information acquired from a circulation state detection means, a control means is based on comparison of information concerned and a preset value, and increases or decreases an extracorporeal circulation flow of blood. Preferably, at least by one side of operation which raises number of rotations of a blood pump, or lowers capacity of a blood reservoir, perform an increase in an extracorporeal circulation flow and reduction of an extracorporeal circulation flow, It constitutes so that at least one side of operation which lowers number of rotations of a pump or raises capacity of a blood reservoir may perform. Thereby, automatic operation of extracorporeal circulation becomes easy.

[0020]It has a means to make a circulation system generate pulsatile flow, by making number of rotations of a blood pump fluctuate periodically, or making capacity of a blood reservoir fluctuate periodically preferably. Thereby, suitable organ perfusion is obtained also in a patient who has complication, such as cerebrovascular disease and renal failure.

[0021]Preferably, among elements arranged in a circuit, at least, a blood pump, a blood reservoir, an artificial lung, and a filter are assembled in one, and are constituted. Thereby, portability increases.

[0022]It has an aeration detection means to detect preferably an aeration arranged at an inflow part of a circuit, and a means to perform at least one side among generating of an alarm, and automatic stay of a pump when it operates according to an output of an aeration detection means and mixing of air into a circuit is detected. Thereby, a serious trouble of mixing in a circuit of air can be prevented, and safety increases.

[0023]

[Mode for carrying out the invention]Hereafter, with reference to Drawings, an outline is indicated about an embodiment of the invention. The extracorporeal circulation equipment in one embodiment of this invention is shown in drawing 1. Although the same number was attached about the same component as the conventional example of drawing 8, the arrangement is not necessarily the same as that of a conventional example.

[0024]All over the circuit from the blood removal pipe 2 to the blood transfusion pipe 10, the filter 9, the main pump 6, the artificial lung 7, and the blood reservoir 3 are arranged as main elements toward the lower stream from the upper stream (blood removal tubeside), and they are connected by the short tube one by one. The drive 38a and the motor for driving 38b are formed in the blood reservoir 3 and the main pump 6, respectively. The circuit internal pressure measurement port 37 which contains a ** sensor in the inflow part (the inflow part said by this

invention refers to some blood circuits of the upstream from a main pump) of a circuit, and the ultrasonic flowmeter probe 31 are arranged. 39 is a controller which makes a control means and is connected with the blood reservoir 3, the main pump 6, the circuit internal pressure measurement port 37, and the ultrasonic flowmeter probe 31 by the wiring 40. 11 shows the flow of the blood in a circuit.

[0025]The blood reservoir 3 has a capacity regulation means for fluctuating capacity to store actively. The drive 38a makes a part of element of a capacity regulation means. Although not illustrated by drawing 1, the blood reservoir 3 has a capacity detection means for detecting capacity. The circuit internal pressure measurement port 37 and the ultrasonic flowmeter probe 31 are the means for detecting a circulation state in a circuit.

[0026]The controller 39 controls capacity and the main pump 6 of the blood reservoir 3 according to an output of the circuit internal pressure measurement port 37 and the ultrasonic flowmeter probe 31. Since the controller 39 holds a reference value for control and performs control based on it, it has a set part for setting up a reference value. Although it is desirable that it is variable as for setting out of a reference value, it may be immobilization depending on conditions of use. It is not indispensable that control by the controller 39 is automatically performed with the output of the circuit internal pressure measurement port 37 and the ultrasonic flowmeter probe 31. Even if it is the composition of operating the controller 39 manually, when the blood reservoir 3 has a capacity regulation means, it is because a main part of an effect of this invention is obtained. Main things of the above elements are explained in full detail below.

[0027]The blood reservoir 3 and the <capacity adjustment> blood reservoir 3 are provided with the following.

The blood chamber 16 which puts in and collects blood as shown in drawing 2.

The pressure control chamber 17 for adjusting the inner capacity of the blood chamber 16. Both ** 16 and 17 are divided by the existing flexible septum (diaphragm) 18. A communication trunk for 3a and 3b to connect with a circuit and 3c are the communication trunks for connecting the pressure control chamber 17 and a capacity adjustment (not shown). Although not illustrated to drawing 2, it has a capacity detection means which detects the stored blood volume. The blood reservoir 3 can adjust the amount of blood storage actively with a capacity adjustment. The thing of various forms can be used as the blood reservoir 3 in this invention, and its capacity adjustment. It explains classifying them.

[0028]The blood reservoir generally built into an extracorporeal circulation circuit has an open sand mold with which air touches blood, and an enclosed type which does not touch air. In conventional extracorporeal circulation equipment, the open sand mold reservoir is incorporated in many cases. However, in order to consider it as simple extracorporeal circulation equipment, the reservoir of the open sand mold which must always supervise the

amount of blood storage of a reservoir is unsuitable. Therefore, in this invention, an enclosed type is preferred. The blood volume of a blood chamber is made to fluctuate actively, and there are a hydrostatic pressure type which adjusts blood volume, and a mechanical cable type which adjusts blood volume second by [direct] carrying out pressure towage of the blood chamber mechanically by carrying out pressure towage of the blood chamber via the first liquid or gas as a capacity adjustment for adjusting.

[0029]In the first hydrostatic pressure type, as shown in drawing 2, two rooms, the blood chamber 16 which puts in blood, and the pressure control chamber 17 which wrap in the whole or a part of blood chamber and into which the gas and liquid for ****** are put, exist. The whole or some of container serves as elasticity, ** of the pressure control chamber 17 is reflected in the blood chamber 16 via the elasticity portion of the blood chamber 16, and, as for the blood chamber 16, the capacity of the blood chamber 16 is adjusted. Drawing 2 shows the blood reservoir which has the existing flexible septum (diaphragm) 18 also in a hydrostatic pressure type.

[0030]A gas or a liquid may be sufficient as the medium of **. If the liquid had mobility, it is [anything] good. Although the degassing physiological saline from which it sterilized and dissolved gas was removed is preferred, the mere water which has not sterilized since blood is not touched directly may be sufficient. Fluids, such as a liquid and a gas, are sent into a pressure control chamber, and the blood reservoir capacity adjustment made to generate suitable ** may be separately installed via a tube, although including in a blood chamber is also possible. The whole system becomes compact when it incorporates. When it is made separate, the blood chamber itself becomes compact and its restriction of the setting position of a blood chamber decreases.

[0031]A blood reservoir capacity adjustment is [anything which may generate suitable **] good. When a medium is air, it is also possible to use the compressor which can adjust **. When a medium is a liquid, there are a system (capacity regulation system) which specifies capacity, such as a syringe and bellows, directly, and a system (pump fluid pressure control mode) which adjusts fluid pressure using a liquid-sending pump.

[0032]The equipment of structure as shown in drawing 3 can be used for a capacity regulation system. The figure (a) shows the equipment which specifies the capacity of a pressure control chamber using the piston 19. The pressure adjusted by the position of the piston 19 is transmitted to the pressure control chamber 17 via the communication trunk 19a. As for the Drawing (b), (c), and (d), capacity is respectively adjusted with the syringe 20, the bellows 21, and the pusher plate 22. It is respectively connected to the pressure control chamber 17 via the communication trunks 20a, 21a, and 22a like (a). The piston 19, the syringe 20, the bellows 21, and the pusher plate 22 are driven by a motor etc.

[0033]In a pump fluid pressure control mode, the capacity of a pressure control chamber is

adjusted using the liquid-sending pump for blood reservoir capacity adjustments. The pump used here is [anything] applicable if liquid sending is possible. As performance called for, it is small and what is excellent in reliability and endurance, is excellent in a response, and can generate high ** regardless of the direction of liquid sending, and cost does not require is good. Specifically, a centrifugal pump, a mixed flow pump, a propeller pump, a friction pump, a gear pump, a roller pump, etc. are mentioned. The switching valve into which a centrifugal pump and a mixed flow pump change a direction since the direction of liquid sending is one way is needed. Drawing 4 (a) and (b) shows the example which used the roller pump 23 and the propeller pump 24, respectively. In a figure, 25 is a liquid-storage room for liquid sending.

[0034]As the second mechanical cable type, composition as shown in drawing 5 can be used. In this case, a blood reservoir capacity adjustment becomes the structure coupled directly with the blood chamber. Drawing 5 (a) is the example which used the piston 12. The blood chamber 12c serves as a container variable in capacity by the position of the piston 12. 12a and 12b are the communication trunks for connecting with a circuit. The Drawing (b), (c), and (d) shows respectively the example in which capacity is adjusted with the syringe 13, the bellows 14, and the pusher plate 15. As a driving source, a motor, an electromagnet, etc. are used and capacity is adjusted by receiving a certain pressure towage.

[0035]In both the first mechanical cable type and the second hydrostatic pressure type, form of a blood chamber must be made into what has a few blood-flow **** part in order to improve anti-thrombus nature. It is thought that the direction of a hydrostatic pressure type has little restriction of the design of a blood chamber, and is superior to a mechanical cable type in anti-thrombus nature. On the other hand, since a mechanism is simple, and part mark also have them and it ends, a mechanical cable type can be manufactured inexpensive. [few] Although the target patient calls on an adult or a child, if the region of accommodation of blood chamber capacity is an adult, it is desirable for it to be able to adjust to 100 ml - 4000 ml.

[0036]The thing of various forms can be used as composition of the capacity detection means which detects the capacity of a blood chamber. If a piston, a syringe, and bellows are used for a blood chamber, capacity is simply detectable with the displacement position of the axis of rotation of a drive motor. The capacity of a blood chamber is measurable also by the method of attaching capacity detection means, such as a hall sensor and an ultrasonic crystal, to a blood chamber or a pressure control chamber, or sending weak current through a blood chamber and measuring impedance and conductance with a current potential plan. When the fluid is liquid in the case of a hydrostatic pressure type, even if it measures the capacity of the liquid discharged via the tube from the regulating chamber with a volume plan, the capacity of a blood chamber can be measured. Since the mensuration of the capacity of the discharged liquid has high flexibility, it can consider many methods, but it is good to measure weight with a weigher simply. The means for supplying detected information is required for the controller 39,

and for that purpose, it constitutes so that a detection result may be outputted as an electrical signal, for example.

[0037]It is possible to include a heat exchanger in the blood reservoir in this invention. There are some methods incorporating a heat exchanger and the following is mentioned as an example. Warming of a living body and cooling are possible for blood ****** by installing the tube made with the construction material which was excellent in heat exchange ability in the blood chamber of a blood reservoir in the first place, and carrying out perfusion of the liquid warmed or cooled in the tube. Warming of a living body and cooling are possible for blood ****** by warming or cooling a pusher plate in the mechanical reservoir which used the pusher plate for the second. If it limits only to warming, how to build a heater into a pusher plate will also be considered, and it will be a simple and effective method. Warming of a living body and cooling are possible for blood ****** by warming or cooling the liquid in a pressure control chamber with a hydraulic system reservoir to the third. It is an effective method, also in order to lose the **** part of blood, to think that anti-thrombus nature becomes high and to improve low invasiveness rather than installing a heat exchanger in a blood chamber.

[0038]The <main pump 6>, next the main pump 6 are explained. Since the blood removal pipe used by MICS etc. is thin, the suitable amount of blood removal may not be obtained. Therefore, it is necessary to add the suitable negative pressure which is not excessive to blood removal. Since addition negative pressure has a limit in fall blood removal, the compulsive blood removal using a pump is preferred. In fall blood removal, in order to enlarge a fall, it is necessary to make an operating table high but, and in compulsive blood removal, the same operating table as the general operation of those other than the heart can be used, and it is effective on employment of an operating room.

[0039]Generally, there are a positive-displacement design and a non-positive-displacement design in a liquid-sending pump. The roller pump mostly used to extracorporeal circulation equipment is classified into a positive displacement pump. the problem at the time of using a positive displacement pump for the main pump of extracorporeal circulation equipment, and moreover installing in the upper stream from a blood reservoir sticks to a blood removal pipe -- etc. -- when the obstacle of a circuit arises, it is that excessive negative pressure occurs in the inflow part of a pump. Excessive negative pressure may damage the body tissue of a blood removal part, and may cause serious troubles, such as drawing in into the circuit of air. for this reason -- sticking fast as a kind of main pump installed in the upper stream from a blood reservoir -- etc. -- the non-positive displacement type pump which excessive negative pressure did not occur at even if it produced, but was excellent in accommodativeness is preferred. The typical things of a non-positive displacement type pump are turbo-pumps, such as a centrifugal pump, a mixed flow pump, and a propeller pump. Although these all can be used for this invention, since the propeller pump needs to make number of rotations very high in order to

generate high **, if hemolysis and endurance are taken into consideration, it is not desirable selection. Therefore, a centrifugal pump and a mixed flow pump are preferred.
[0040]Control of a circulation state by the controller 39 in <the controller 39 and a circulation state detection means>, next the extracorporeal circulation equipment of this invention is explained. In order to make operation of extracorporeal circulation equipment simple and to Automatic Control Division-ize it most preferably, control by a computer is required. It is also effective in control to consider and combine some methods.
[0041]the 1st method is based on ** -- it sticks fast and they are detection and prevention. That is, if monitor inlet pressure of a circuit, it inhales from a pressure wave form, **** is detected and inhaled and **** appears, control which lowers number of rotations of a pump or lowers capacity of a blood reservoir will be performed. Reflecting venous pressure, if ** of an inflow part is normal, it serves as a steady flow which does not almost have pulse pressure. However, if a blood removal pipe sucks up and **** arises, disorder of an unusual pressure wave form characterized by rapid fall of ** will arise. This serves as increase of pulse pressure, increase of a pressure change (increase of an absolute value of ********), and change of **********, and appears. A ** sensor of the pressure measuring port 37 which constitutes a circulation state detection means detects this, and information acquired by it is transmitted to the controller 39 which is a control means. A computer is built into the controller 39, and using information acquired from a ** sensor, the main pump 6 and/or a blood reservoir are adjusted so that blood may flow through inside of extracorporeal circulation equipment favorably.
[0042]If the 2nd method sets up a lower limit value of inlet pressure and it is less than a preset value, it will be the controlling method which lowers number of rotations of a pump or lowers capacity of a blood reservoir. Although a certain amount of [a lower limit value] negative pressure is unavoidable, since it becomes origin of obstacles, such as cavitation generating of a main pump and drawing in into a circuit of unexpected air, negative pressure which is less than -100mmHg must be prevented. In order to measure inlet pressure of a circuit as a circulation state detection means like the 1st method also in this case, the ** sensor 37 shown in drawing 1 is used. It is required for the controller 39 to have a means to set up a lower limit value of inlet pressure.
[0043]The 3rd method will be the controlling method which lowers the number of rotations of a pump or lowers the capacity of a blood reservoir, if measure the consumed electric current or electric power of a blood pump, a blood removal part inhales from the waveform of the consumed electric current or electric power, **** is detected and inhaled and **** appears. Although this is fundamentally the same as the 1st method, in order to use the in-house data which the motor of a pump has, a special sensor is not needed, but it leads to reduction of cost. In this case, since the consumed electric current and power consumption of a drive (motor) which are driving the blood pump must be measured, a means to monitor the current

or electric power of a motor of a pump is needed as a circulation state detection means.
[0044]If a living body's arterial pressure and extracorporeal circulation blood flow rate used as a target are set up and both this arterial pressure, this flow, or either is less than a preset value, the 4th method, If pump rotation frequency is raised, or the capacity of a blood reservoir is lowered and both this arterial pressure and this flow exceed a preset value, it will be the controlling method which lowers pump rotation frequency or raises the capacity of a blood reservoir. The arterial pressure and the extracorporeal circulation blood flow rate to set up must be determined according to a living body's individual difference or the condition of the technique and a living body, and cannot consider setting it as the same value in any situations. However, it is possible to decide target arterial pressure suitable for each case and an extracorporeal circulation blood flow rate to be beforehand, and it is not necessary to change a preset value frequently during extracorporeal circulation implementation. It is not especially limited which shall be given priority to and adjusted between pump rotation frequency and blood reservoir capacity, but it is both possible.
[0045]Until it sets up optimum upper limit (it is described as Arpm) of pump rotation frequency and exceeds Arpm as one desirable method, It controls towards giving priority to blood reservoir capacity, increasing capacity, and considering it as the maximum (full blood removal), and if it will be necessary to exceed Arpm in order to make a blood flow rate increase, how to reduce blood reservoir capacity without raising number of rotations can be considered. Administration of a pressure-up agent or vasodepressor is also required during extracorporeal circulation, and suitable treatment is needed suitably. If a living body's arterial pressure and an extracorporeal circulation blood flow rate are measurable as a circulation state detection means provided in extracorporeal circulation equipment in the case of the 4th method, a pressure (blood) monitor line, a blood flow merer, etc. which it was not limited in particular, for example, were formed in blood circuits will be mentioned.
[0046]Reduction of a fill ration of an extracorporeal circulation circuit is attained by simplifying a <simplification of circuit and system> circuit and shortening a tube as much as possible. Reduction in a fill ration can be contributed to low invasiveness by suppressing generating of an edema by hemodilution and reducing the necessity for blood transfusion substantially. By assembling a circuit on a manufacture level beforehand, a labor required for an assembly is omitted and it is connected with human laborsaving and cost reduction. If restoration in a circuit is also substituted for a manufacture level, preparation further before an operation is mitigable. Conventional extracorporeal circulation equipment is large-sized, and a large space needed to be secured, and since movement was difficult, it had interfered with elastic employment of equipment. In this invention, a circuit and a drive are designed compactly, it is possible to secure portability and these problems are also solved.
[0047]In a patient who has complication, such as <pulsation and oscillating additional-

equipment> cerebrovascular disease and renal failure, the validity of extracorporeal circulation which has pulsatile flow is accepted. Therefore, also in this invention, it is effective to enable addition of pulsation and vibration, also in order to attain low invasion-ization. The following can be considered to a method of adding pulsation and vibration. It is the method of generating pulsatile flow, by making number of rotations of a pump 1st fluctuate periodically. It is the method of generating pulsatile flow thru/or vibration, by making the 2nd fluctuate capacity of a blood reservoir periodically. Especially the latter is the new method which employed efficiently the feature of a blood reservoir that capacity could be adjusted actively. It is also possible to use the 1st and the 2nd method together, and it is effective.

[0048]Antithrombotic processing is performed to a blood contacting surface of a <anti-thrombus processing> circuit. In this invention, it is a complete rebreathing system which does not touch air, and in order to use a blood reservoir which improved anti-thrombus nature with few blood-flow **** parts, antithrombotic processing and extracorporeal circulation in conjointly more few anticoagulants become possible. By the usual extracorporeal circulation, anticoagulants, such as heparin, are prescribed for the patient and, specifically, operation of a place which keeps activated coagulation time at 400 seconds or more is enabled in 250 seconds from 200 seconds. As a result, bleeding decreases, and shortening of operation time, a fall of the necessity for blood transfusion, etc. are effective in order to improve the low invasiveness of extracorporeal circulation equipment.

[0049]As an example is shown in <separation type navigational panel> drawing 6, the separation type navigational panel 26 which can be installed in a field of operation is used, and operation required for control presupposes that it is possible from a field of operation. The necessity that this provides a special extracorporeal circulation operator decreases, and it leads to human laborsaving. The separation type navigational panel can consider what hung the transparent sterilization covering 27 on the touch-sensitive liquid crystal display. while it installs in the place which the way person's 28 (or the first assistant) hand reaches and the surveillance and control of extracorporeal circulation perform an operation using a sound or a sound -- **** -- a user interface which becomes possible is preferred.

[0050]Operation of <remote control function> extracorporeal circulation will serve as surveillance from remoteness controllable from hand control, if it automates more. If a concrete example is shown, data required for the surveillance and control of extracorporeal circulation will be put on a network by the standards (for example, combination of GPIB and TCP/IP, etc.) of a flexible measuring instrument and communication, and batch management will be carried out at an extracorporeal circulation central control room. Many pieces of extracorporeal circulation equipment is the effective methods of leading to human laborsaving in the large-scale hospital currently operated simultaneously. Since it becomes possible to record and save all the data, it is useful for scientific practical use.

[0051]An aeration into a <aeration arrester in circuit> circuit is one of the serious troubles which arise during extracorporeal circulation operation. I hear that that it is a simple system has so high safety that it can be used simple, and there is. Some methods can be considered in the ways of coping to an aeration. A bubble detection function is given to the flow instrument the 1st, using an ultrasonic flowmeter as a flow instrument which monitors an extracorporeal circulation blood flow rate. If the probe 31 of an ultrasonic flowmeter is attached to the inflow part of a circuit and a bubble is detected as shown in drawing 1, an alarm will be emitted promptly and it will be coped with.
[0052]The filter 32 is installed in a circuit inflow part the 2nd. The filter 32 is installed in the highest place of a circuit, and it is made for air to accumulate. If the optical sensor 33 for detecting air for an example in the filter 32 as shown in drawing 7 is installed and air accumulates [3rd], this will be detected, an alarm will be emitted promptly and a pump will be stopped. The port 34 for discharging air is installed in the upper tip of the filter 32, and the port 34 is connected [4th] to the suction circuit 35. Usually, this port 34 is intercepted by the breaker 36. If the filter 32 is covered with air, interception of a port will be canceled hand control or automatically promptly, and suction discharging of the air will be carried out outside. It is possible to combine the plurality of these methods or all, and it is effective. 30 in drawing 7 shows the flow of blood.
[0053]Some peripheral equipment is needed for <linkage with peripheral equipment> extracorporeal circulation equipment by the technique. That is, they are the reservoir for a suction circuit and suction circuits, hemoconcentration equipment (cell SEBA, ultrafiltration equipment), a myocardium protection liquid circuit and an injector, a vent circuit, etc. In this invention, it is effective to aim at linkage with these pieces of equipment.
[0054](Concrete embodiment) The more concrete embodiment which was suitable for below at it as an example of an operation which uses the extracorporeal circulation equipment of this invention on the assumption that the mitral valve operation under MICS is described.
[0055]As shown in drawing 1 toward the lower stream (blood transfusion tubeside) from the upper stream (blood removal tubeside) of a <composition of extracorporeal circulation equipment> circuit, the filter 9, the pump 6, the artificial lung 7, and the blood reservoir 3 are connected by a short tube one by one. These are compact and what has the few amount of filling liquid is preferred. If these are already assembled at the time of shipment, they are convenient. These are preferred, a compact thing and installing in the sterilization field of operation of an operation conjointly can also be sterilized and supplied, and it is effective. If it can install in a sterilization field of operation, the tube for connecting with a blood removal pipe or a blood transfusion pipe can be shortened further, and the whole amount of filling liquid can be lessened further. Capture and interception of the air which mixed the filter in the circuit with removal of the impurity are the purposes. In order to capture air, it installs in the highest

position in all the circuits.

[0056]Although its turbo-pump is preferred, if a pump is a small mixed flow pump, it is still more preferred. If sterilization with waterproofness is possible for the motor for driving a pump, it can be installed in a sterilization field of operation, and its handling is convenient. Or handling is still more convenient if it has sterilized by the same product made from disposal as a pump. A compact thing is preferred although anythings can use an artificial lung. Especially the thing that was excellent in gas exchange ability or haemocompatibility is preferred, and its membrane type is better than this point to an air-bubbles type. A blood reservoir measures mechanically the blood volume by which blood storage was carried out, and makes it what can be adjusted. Although various modes can be considered, an example is given about each of a mechanical cable type and a hydraulic system.

[0057]A mechanical cable type uses a pusher plate. The blood chamber of a blood reservoir consists of hard housing and a flexible film. A blood reservoir drive serves as a motor for pressing and towing the hard pusher plate and pusher plate for pressing the flexible film of a blood chamber from a motor controller. The pusher plate must be what can press the flexible film of a blood reservoir uniformly. The load concerning a pusher plate becomes uniform and the direction in which the blood reservoir was installed so that a pusher plate might become level to a floor is preferred. It will warm, if it will be necessary to embed a heater and to raise a patient's body temperature into a PUSHA plate. Although the motor must have a means to change rotation into a straight-line motion, the linear motor which produces a straight-line motion from the start may be used. A motor controller mainly performs position control of a motor. Capacity Measurement Division of a blood chamber is performed by detecting the position of a motor.

[0058]In a fluid pressure type, a flexible septum (diaphragm) is put on an inside of a transparent hard plastic container, and two cavities, a blood chamber and a pressure control chamber, are provided. A pressure control chamber is connected to a liquid-storage room for liquid sending by connection tube. A pressure control chamber, a liquid-storage room, and a connection tube are filled with a liquid for liquid sending (tap water is used). A roller pump is installed in the middle of a connection tube, by making for Masakata or an opposite direction rotate a roller pump, capacity of a pressure control chamber is adjusted and, as a result, capacity of a blood chamber is adjusted. By a fluid pressure formula, what kind of angle may be sufficient as installation of a blood reservoir to a floor, and its flexibility of installation is high. It will warm, if it will be necessary to embed a heater and to raise a patient's body temperature into a pressure control chamber. As shown in drawing 1, the circuit internal pressure measurement port 37 is established in an inflow part, and inflow part circuit internal pressure is monitored. An ultrasonic flowmeter (with bubble detection function) probe is attached to an inflow part.

[0059]The function to make extracorporeal circulation equipment generate pulsatile flow is added. Powerful pulsation addition capability is obtained by taking a synchronization periodically and changing the number of rotations of the motor of a pump, and the capacity of a blood reservoir. Different consideration from conventional extracorporeal circulation equipment is required for the connection order foreword of extracorporeal circulation equipment each component of this invention. Since capture and interception of the air mixed in the circuit are the big purposes, a filter is installed in the style of Mogami. In negative pressure and the lower stream, the upper stream serves as positive pressure from the pump. Therefore, an artificial lung is put on the positive pressure side. If a blood reservoir is the above-mentioned mechanical cable type, it is more desirable to install it in the positive pressure side, although it can install in both negative pressure and positive pressure. If the inside of a blood chamber is positive pressure, it becomes unnecessary for the Reason to carry out forcible towage of the pusher plate, and to carry out adhesion fixing of between the flexible film of a blood reservoir, and pusher plates, and it is assembly top convenience. In order to generate pulsatile flow using a blood reservoir, it is desirable to install a blood reservoir downstream most. As mentioned above, it is desirable to become the order of a filter, a pump, an artificial lung, and a blood reservoir from the upper stream (blood removal tubeside) of a circuit toward the lower stream (blood transfusion tubeside).
[0060]There are many functions required for the controller for driving and controlling extracorporeal circulation equipment. In this function, it controls with rotation of a pump motor, and control and the drive of a blood reservoir drive motor at least, External data inputs, such as communication with the transducer for inflow part circuit internal pressure measurement, and amplifier, an ultrasonic flowmeter (with a bubble detection function) and a separation type navigational panel and a patient's blood pressure, control of the whole system, etc. are included. An interlocking function with the reservoir for a suction circuit and suction circuits, hemoconcentration equipment (cell SEBA, ultrafiltration equipment), a myocardium protection liquid circuit and an injector, a vent circuit, etc. is also effective. The input output function of the surveillance and control data through a network is also effective. In order to improve space-saving [of a system], and portability, the small and movable thing of the controller is preferred.

[0061]A filter, a pump, an artificial lung, and a blood reservoir which constitute extracorporeal circulation equipment of <setting of operation> this invention can be installed in a sterilization field of operation by assembling at the time of shipment and making sterilization complete in a short time. Before installing restoration in a circuit, and air extraction in a sterilization field of operation, they are possible also later. If a silicon film production type lung which a liquid break through does not generate is used, it will be possible to also make it already complete to restoration at the time of shipment, and it will lead to large laborsaving. A port for air extraction

is established in a filter and a blood reservoir. An extracorporeal circulation equipment controller is installed near the operating table. Inflow part circuit internal pressure is monitored and a sterilized ultrasonic flowmeter (with bubble detection function) probe is attached. A suction circuit, a myocardium protection liquid circuit, etc. are prepared. Transparent sterilization covering is covered over a separation type navigational panel, and it installs in a place which a way person tends to operate. Extracorporeal circulation is operated under cooperation of a way person, an operation assistant, and an anesthesiologist. Therefore, a special staff only for extracorporeal circulation device operation is not stationed.

[0062]A procedure of a mitral valve operation under MICS using extracorporeal circulation equipment of <implementation of operation> this invention is mentioned as an example. Skin incision is shortened as much as possible, the partial median sternotomy is performed, and the heart is exposed. Small incision is added to a right inguinal region, and a femoral artery and vein is exposed. A blood transfusion pipe is inserted in a femoral artery, and a blood removal pipe is inserted in an inferior vena cava from a femoral vein. A blood removal pipe is directly inserted in superior vena cava from a sternotomy part. Double snare on a tape is hung on a right-atrium close relationship of superior vena cava and an inferior vena cava, and it is considered as tourniquet. Interception of this tourniquet must fully be possible so that compulsive blood removal by negative pressure of a vein may not draw air, either. Although thickness of a blood removal pipe changes with patients, insertion is also simple for a thin thing and it does not become the hindrance of a view. KANYURA for myocardium protection liquid pouring is installed in an ascending aorta. It fills up and an extracorporeal circulation circuit which air extraction ended, and a blood transfusion pipe and a blood removal pipe which were attached to a patient are connected. It checks that there is no problem in the whole circuit, and extracorporeal circulation is started.

[0063]Extracorporeal circulation makes automatic operation possible fundamentally. On condition that it is not less than the value which patient arterial pressure set up beforehand, pump rotation frequency is raised until a set flow rate is obtained. If a set flow rate is obtained, the capacity of a blood reservoir will be raised next. As long as patient arterial pressure and a flow allow, the capacity of the blood reservoir is raised. It checks that stable extracorporeal circulation operation is obtained, an ascending aorta is intercepted, myocardium protection liquid is poured in, and the heart is stopped. Myocardium protection liquid, bleeding, etc. which have carried out perfusion are attracted, and are brought together in the reservoir for suction circuits. The collected liquid is processed with hemoconcentration equipment (cell SEBA, a ultrafiltration equipment, etc.), and is transfused into a patient. Since operation of hemoconcentration equipment is easy, even if it is not the extracorporeal circulation engineer trained specially, it can be enforced.

[0064]Up-and-down vena cava are intercepted and it results in a mitral valve by the right

atrium and the atrioseptostomy, or left-atrium incision. Even if the method of a mitral valve operation, for example, mitral valve replacement, and mitral annuloplasty is MICS, it is not different from usual. The air after the end of treatment of a mitral valve and in the heart is removed enough, ascending aorta interception is canceled, and suture closing of the cardiotomy part is carried out thoroughly. Up-and-down vena-cava interception is canceled, an extracorporeal circulation flow is lowered, and extracorporeal circulation will be ended if the heart beat is enough. Since it is required to carry out manually to some extent and ** is after the end of mind operation, a way person and an operation assistant can enforce the separating operation from extracorporeal circulation.

[0065]The serious trouble under <safety measures to aeration> extracorporeal circulation enforcement has the aeration in a circuit. Especially when the blood reservoir of an enclosed type is used, since there is a danger of sending into a patient's artery if air is not removed promptly, it is a problem. The mixing part of air is an upstream negative pressure side from a pump. Therefore, it is important not to establish an unnecessary port in the negative pressure side. The terminal area of a circuit also needs a device from which it does not separate simply. Even if satisfactory in the circuit itself, air may be drawn in a blood removal pipe from the inside of the heart. Therefore, interception of up-and-down vena cava must be made into a positive thing.

[0066]A pump is controlled and inhaled and **** is prevented so that it may not become negative pressure with excessive inflow part circuit internal pressure. Even if it performs these safety measures, in consideration of a possibility that air will mix, a security apparatus is established further. The mixed air is detected by the bubble detection function of an ultrasonic flowmeter, sounds an alarm promptly, lowers the number of rotations of a pump, and reduces a flow. However, a stop is not carried out. Since a stop of a pump means circulation interception, the easy pump stop cannot say it as suitable correspondence. If the sensor of air detection is attached also to a filter and air accumulates more than fixed, a pump will be stopped promptly. The port of air extraction is established in the upper bed of the filter, a suction circuit is connected beforehand, and it usually intercepts. If air is detected by a bubble detection function or air accumulates in a filter, by automatic or manual operation, the interception to a suction circuit will be canceled and air will be removed outside a circuit. Also to a blood reservoir, an air extraction port is established in an upper bed, and it escapes from air if needed.

[Translation done.]

* NOTICES *

1.This document has been translated by computer. So the translation may not reflect the original precisely.
2.**** shows the word which can not be translated.
3.In the drawings, any words are not translated.

DESCRIPTION OF DRAWINGS

[Brief Description of the Drawings]
[Drawing 1]The mimetic diagram showing the extracorporeal circulation equipment in the embodiment of this invention
[Drawing 2]The mimetic diagram showing the hydrostatic pressure type capacity regulation blood reservoir in the embodiment of this invention
[Drawing 3]The mimetic diagram showing the capacity adjustment (capacity regulation system) of various kinds of fluid (liquid) pressure type capacity regulation blood reservoirs in the embodiment of this invention
[Drawing 4]The mimetic diagram showing the capacity adjustment (pump water pressure control mode) of various kinds of fluid (liquid) pressure type capacity regulation blood reservoirs in the embodiment of this invention
[Drawing 5]The mimetic diagram showing various kinds of mechanical capacity regulation blood reservoirs in the embodiment of this invention
[Drawing 6]The mimetic diagram showing the outline of the separation type navigational panel in the embodiment of this invention
[Drawing 7]The mimetic diagram showing the aeration arrester in the embodiment of this invention
[Drawing 8]The mimetic diagram showing the extracorporeal circulation equipment of a conventional example
[Explanations of letters or numerals]
2 Blood removal pipe
3 Blood reservoir
4 Heating-cooling equipment
5 Heat exchanger
6 Main pump

7 Artificial lung
8 The flow of the gas to an artificial lung
9 Filter
10 Blood transfusion pipe
11 The flow of the blood in a circuit
12 Piston
13 Syringe
14 Bellows
15 Pusher plate
16 Blood chamber
17 Pressure control chamber
18 Diaphragm
19 Piston
20 Syringe
21 Bellows
22 Pusher plate
23 Roller pump
24 Propeller pump
25 The liquid-storage room for liquid sending
26 Separation type navigational panel
27 Transparent sheet
30 The flow of blood
31 Ultrasonic flowmeter probe
32 Filter
33 Optical sensor
34 The port for discharging air
35 Suction circuit
36 Circuit breaker
37 Circuit internal pressure measurement port
38a Drive
38b Motor for driving
39 Controller
40 Wiring

[Translation done.]

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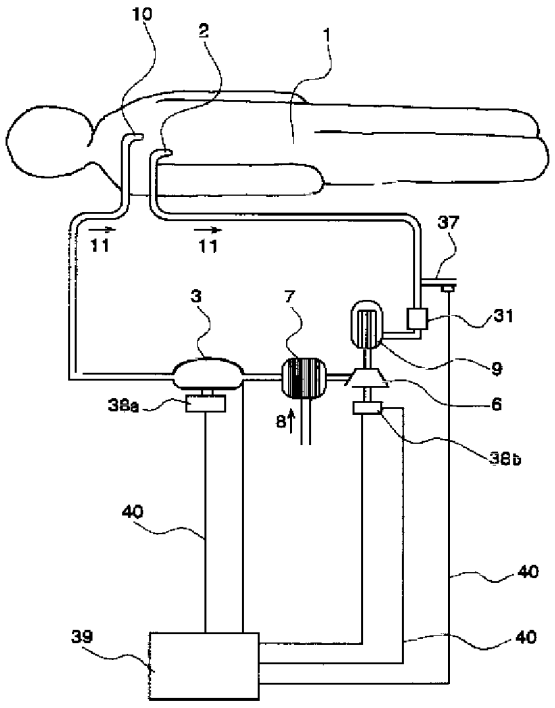
(54)【発明の名称】　制御機能を備えた体外循環装置

(57)【要約】
【課題】　簡便で自動制御可能な体外循環装置を提供する。また、簡素な構成で、低侵襲な体外循環装置を提供する。
【解決手段】　回路内に所定の要素を配置して血液を体外循環させるように構成した体外循環装置において、血液ポンプ６と、貯留する容量を能動的に増減するための容量調節手段および容量を検出するための容量検出手段を有する血液リザーバ３と、容量検出手段の出力が供給されて容量調節手段を介して血液リザーバの容量を制御するとともに、血液ポンプの流量を制御する制御手段３９とを備える。制御手段３９により、少なくとも前記容量調節手段を制御して、回路内の循環状態を調節することが可能なように構成される。



【特許請求の範囲】
【請求項１】　回路内に所定の要素を配置して血液を体外循環させるように構成した体外循環装置において、
血液ポンプと、
貯留する容量を能動的に増減するための容量調節手段、および前記容量を検出するための容量検出手段を有する血液リザーバと、
前記容量検出手段の出力が供給されて前記容量調節手段を介して前記血液リザーバの容量を制御するとともに、前記血液ポンプの流量を制御する制御手段とを備え、
前記制御手段により、少なくとも前記容量調節手段を制御して、回路内の循環状態を調節することが可能なように構成したことを特徴とする体外循環装置。
【請求項２】　回路内の循環状態を検知する循環状態検知手段を備え、制御手段が、前記循環状態検知手段が検知した出力に応じて、前記回路内の循環状態を調節する請求項１に記載の体外循環装置。
【請求項３】　血液ポンプが非容積型血液ポンプである請求項１または２に記載の体外循環装置。
【請求項４】　血液リザーバは、血液を貯留する血液室と、その血液室を蔽う外部ハウジングとを有し、前記血液室はその室内の血液が外気と接しない閉鎖式であり、容量調節手段が、前記血液室の外壁の少なくとも一部を変形させることにより容量を調節するように構成された請求項１～３のいずれかに記載の体外循環装置。
【請求項５】　血液リザーバは、血液を貯留する血液室と、その血液室に隣接して設けた前記血液室内の血液容量を調節する圧調節室と、これらの２室を蔽う外部ハウジングとを有し、前記血液室はその室内の血液が外気と接しない閉鎖式であり、容量調節手段が、前記血液室の外壁の少なくとも一部を変形させることにより容量を調節するように構成された請求項１～３のいずれかに記載の体外循環装置。
【請求項６】　容量検出手段は、血液室の外壁の変形状態に基づき血液室の血液容量を検出するように構成された請求項４または５に記載の体外循環装置。
【請求項７】　血液室の少なくとも一部が可撓性の隔壁であるダイアフラムにより形成された請求項４～６のいずれかに記載の体外循環装置。
【請求項８】　容量調節手段は硬性の板からなるプッシャープレートを有し、そのプッシャープレートが隔壁を圧迫もしくは牽引することにより、血液室の容量を調節する請求項７に記載の体外循環装置。
【請求項９】　回路内において、非容積型ポンプが血液リザーバの上流側にのみ設置されている請求項３～８のいずれかに記載の体外循環装置。
【請求項１０】　循環状態検知手段が、流入部に設けられた圧力センサである請求項２に記載の体外循環装置。
【請求項１１】　循環状態検知手段が、血液ポンプの駆動装置に接続された消費電流および／または消費電力モニターの出力に基づき循環状態を検知するように構成された請求項２に記載の体外循環装置。
【請求項１２】　循環状態検知手段が、回路内から得られたデータに基づき、生体の動脈圧および／または体外循環血液流量を推定する循環状態推定手段を有する請求項２、１０または１１のいずれかに記載の体外循環装置。
【請求項１３】　制御手段は、循環状態検知手段から得られる情報に基づき脱血部の吸い付きを検出し、該吸い付きが検出されたとき、血液ポンプの回転数を下げるか、もしくは血液リザーバの容量を下げるように制御する請求項２、または１０～１２のいずれかに記載の体外循環装置。
【請求項１４】　循環状態検知手段から得られる情報に関して臨界値または目標となる範囲を示す設定値を設定する手段を有し、制御手段は、前記情報と前記設定値の比較に基づき、血液の体外循環流量を増加または減少させる請求項２、または１０～１３のいずれかに記載の体外循環装置。
【請求項１５】　体外循環流量の増加は、血液ポンプの回転数を上げるか、もしくは血液リザーバの容量を下げる操作の少なくとも一方によって行い、前記体外循環流量の減少は、前記ポンプの回転数を下げるか、もしくは前記血液リザーバの容量を上げる操作の少なくとも一方によって行う請求項１４に記載の体外循環装置。
【請求項１６】　血液ポンプの回転数を周期的に増減させることにより、循環システムに拍動流を発生させる手段を備えた請求項１～１５のいずれかに記載の体外循環装置。
【請求項１７】　血液リザーバの容量を周期的に増減させることにより、循環システムに拍動流ないし振動を発生させる手段を備えた請求項１～１６のいずれかに記載の体外循環装置。
【請求項１８】　回路内に配置される要素のうち少なくとも、血液ポンプ、血液リザーバ、人工肺、およびフィルターを一体的に組み立てて構成した請求項１～１７のいずれかに記載の体外循環装置。
【請求項１９】　回路の流入部に配置された空気混入を検出する空気混入検出手段と、前記空気混入検出手段の出力に応じて作動し、回路内への空気の混入が検出されたとき、警報の発生およびポンプの自動停止のうち少なくとも一方を行う手段とを備えた請求項１～１８のいずれかに記載の体外循環装置。
【発明の詳細な説明】
【０００１】
【発明の属する技術分野】本発明は、血液の体外循環装置、特に、循環状態を制御する機能を備えた簡便で低侵襲な体外循環装置に関する。
【０００２】
【従来の技術】心臓・大血管の手術では、一時的に心臓

を停止あるいは停止に近い状態にする必要があり、心臓と肺の機能を機械により肩代わりさせるため、体外循環装置を用いる。従来使用されている体外循環装置は、図８に示すように、主要な要素として、脱血管２、血液リザーバ８３、熱交換器５、メインポンプ８６、人工肺７、フィルタ９、および送血管１０を備え、それらの要素を血液回路中に順次配置した構成である。

【０００３】脱血管２は、患者１の上下大静脈や右心房に挿入され、流量を多くとるため可及的に太いものが用いられる。血液リザーバ８３は、血液が空気に接する開放型が多く用いられており、患者１と血液リザーバ８３の落差を利用した落差脱血により、脱血管を通して血液が流入する。少数ではあるが、血液が空気に接しない閉鎖型の血液リザーバも用いられ、血液ポンプを用いた強制脱血により、脱血管を通して血液が流入するものもある。開放型の血液リザーバでは、貯液された血液容量が低下すると回路内に空気を送り込む危険が増すため、警報を発するものがあるが、能動的に容量を調節するものは知られていない。熱交換器５は血液リザーバ内に設置されることが多く、金属製のチューブに、加温冷却装置４により加温ないし冷却された液体（通常は水道水）を潅流し、血液を加温ないし冷却する。メインポンプ８６は、ローラーポンプあるいは遠心ポンプが用いられ、血液リザーバの下流に設置されている。メインポンプが血液リザーバの上流に設置されている例はない。体外循環装置全体は大型であり、一般の手術に比べて広いスペースを確保しておく必要がある。また、大型の機械のため持ち運びには適さず、常時手術場に設置されている。

【０００４】体外循環装置の操作は、そのための特別な人員を配置して行われる。体外循環操作者は、通常、体外循環技術者がその任に当たるが、医師が行うこともある。いずれにせよ、高度な技術を獲得した特別な人員が必要である。体外循環操作者は手術台の横に位置し、決して手術操作に加わったり、遠隔地に位置することはない。体外循環操作者は、脱血の程度、生体の動脈圧を見ながら、至適な体外循環血液流量を考慮し、手動操作により、血液リザーバの容量やポンプ流量の調整を行っている。そのため、体外循環施行中に体外循環操作者が体外循環装置から離れることはできない。

【０００５】ところで、人的、経済的な医療資源を有効に活用するために、外科領域においては低侵襲手術が積極的に導入されている。心臓外科領域での低侵襲手術はＭＩＣＳ（Minimally Invasive Cardiac Surgery；低侵襲心臓手術）と呼ばれる。ＭＩＣＳでは、侵襲を減らすために全長にわたる胸骨正中切開は行われず、皮膚切開は極力短くされる。そのため、心臓を露出するための視野が制限される。よって、体外循環装置に用いられる脱血管は、視野の妨げにならない細いものが好まれる。

【０００６】

【発明が解決しようとする課題】本発明の主要な目的は、操作が容易で運転の自動化も可能な体外循環装置を提供することである。また、低侵襲な体外循環を可能とする体外循環装置を実現することも付随する重要な目的である。本発明が解決しようとする課題に関して、以下に詳述する。

【０００７】＜省力化・易操作性＞従来、心臓・大血管手術において体外循環が必要な場合には、体外循環を操作するための人員が必要であった。しかも、体外循環装置の運転は、操作が煩雑で高度な技術を要し、経験が必要である。従って本発明は、運転を機械的に制御し、操作が容易・簡便で、省力化が可能な装置を提供することを目的とする。

【０００８】＜低侵襲性＞体外循環が生体に与える副作用として、血液の希釈、大量の抗凝固剤投与による出血、血球破壊による溶血や炎症の惹起、非生理的な定常流による臓器血流の低下などが挙げられる。これらの副作用を減弱するため、低侵襲性を実現できる体外循環装置が望ましい。一方、ＭＩＣＳなどで用いられている脱血管は細いため、適切な脱血量が得られないことがある。従って本発明は、低侵襲性を確保しつつも、循環システムを流れる血液流量を確保することのできる装置を提供することを目的とする。

【０００９】＜安全性＞従来の体外循環装置は、安全機構が十分に備わっていないため、安全性は主に体外循環を操作する技術者の技能に依存している。従って本発明は、ハードウェア的あるいはソフトウェア的に安全機構を備えた装置を提供することを目的とする。

【００１０】＜小型化、可搬性の確保＞従来の体外循環装置は大型であり、広いスペースを確保する必要がある。また、移動は困難であり、器材の弾力ある運用に支障を来している。従って本発明は、循環システムの小型化や易動性の改善を目的とする。

【００１１】

【課題を解決するための手段】上記の課題を解決するために、本発明の体外循環装置は、回路内に所定の要素を配置して血液を体外循環させるように構成した体外循環装置であって、血液ポンプと、貯留する容量を能動的に増減するための容量調節手段および容量を検出するための容量検出手段を有する血液リザーバと、容量検出手段の出力が供給されて容量調節手段を介して血液リザーバの容量を制御するとともに、血液ポンプの流量を制御するための制御手段とを備える。制御手段により、少なくとも容量調節手段を制御して、回路内の循環状態を調節することが可能なように構成される。この構成によれば、血液リザーバが容量調節手段と容量検出手段とを有し、その容量を制御することが可能なことにより、装置の運転は操作者の高度な技術を必要とせず、容易で簡便なものとなる。

【００１２】好ましくは、回路内の循環状態を検知する循環状態検知手段を備え、制御手段が、循環状態検知手

段が検知した出力に応じて、回路内の循環状態を調節するように構成する。それにより、自動運転が容易になる。

【００１３】また、好ましくは、血液ポンプを非容積型血液ポンプとする。非容積型血液ポンプを用いることにより、脱血管の吸い付きなどのトラブル時に過大な陰圧が発生することを防止でき、安全性が高まり、また、小型で低侵襲なシステムを構築することが可能である。

【００１４】更に、好ましくは、血液リザーバを、血液を貯留する血液室と、その血液室を蔽う外部ハウジングとを有する構成とする。あるいは、血液を貯留する血液室と、その血液室に隣接して設けた血液室内の血液容量を調節する圧調節室と、これらの２室を蔽う外部ハウジングとを有する構成とする。いずれの場合も、血液室はその室内の血液が外気と接しない閉鎖式とする。血液リザーバを閉鎖式とすることにより、開放型と比べて安全性の観点から強制脱血が容易となる。従って、大流量を確保し、低侵襲性を実現することも容易である。また、小型化も容易となる。更に、容量調節手段は、血液室の外壁の少なくとも一部を変形させることにより容量を調節するように構成する。

【００１５】これらの構成において、容量検出手段は、血液室の外壁の変形状態に基づき血液室の血液容量を検出するように構成することが好ましい。それにより、容量の調節、および容量の計測を、簡単な構成で行うことができる。また、血液室の少なくとも一部を可撓性の隔壁であるダイアフラムにより形成することが好ましい。この構成によれば、ダイアフラムを気体あるいは液体で圧迫もしくは牽引することにより、容量調節、および容量検出を簡単に構成で行うことができるとともに、血液リザーバの形状や設置場所の自由度が高い。更に、容量調節手段は硬性の板からなるプッシャープレートを有し、そのプッシャープレートが隔壁を圧迫もしくは牽引することにより、血液室の容量を調節するように構成することが好ましい。それにより、容量調節のための機構を単純にでき、装置を安価に製作できる。

【００１６】更に、好ましくは、回路内において、非容積型ポンプが血液リザーバの上流側にのみ設置する。この構成によれば、陰圧による強制脱血が容易であり、脱血管を細くでき、低侵襲性の実現に有利である。

【００１７】更に、好ましくは、循環状態検知手段を、流入部に設けられた圧力センサで構成する。また、循環状態検知手段が、血液ポンプの駆動装置に接続された消費電流および／または消費電力モニターの出力に基づき循環状態を検知するように構成する。更に、好ましくは、循環状態検知手段が、回路内から得られたデータに基づき、生体の動脈圧および／または体外循環血液流量を推定する循環状態推定手段を有する。これらの構成によれば、脱血管に過大な陰圧がかかることを防止でき、空気を引き込む可能性が少なくなり、安全性が高まる。血液ポンプの消費電流等から循環状態を検知する構成の場合は、センサを必要としないためシステムを安価に製作可能である。

【００１８】更に、好ましくは、制御手段は、循環状態検知手段から得られる情報に基づき脱血部の吸い付きを検出し、該吸い付きが検出されたとき、血液ポンプの回転数を下げるか、もしくは血液リザーバの容量を下げるように制御する。それにより、脱血部の吸い付きに容易に対処でき、吸い付きが予防できて安全性が高まる。

【００１９】更に、好ましくは、循環状態検知手段から得られる情報に関して臨界値または目標となる範囲を示す設定値を設定する手段を有し、制御手段は、当該情報と設定値の比較に基づき、血液の体外循環流量を増加または減少させる。更に、好ましくは、体外循環流量の増加は、血液ポンプの回転数を上げるか、もしくは血液リザーバの容量を下げる操作の少なくとも一方によって行い、体外循環流量の減少は、ポンプの回転数を下げるか、もしくは血液リザーバの容量を上げる操作の少なくとも一方によって行うように構成する。それにより、体外循環の自動運転が容易になる。

【００２０】更に、好ましくは、血液ポンプの回転数を周期的に増減させるか、もしくは血液リザーバの容量を周期的に増減させることにより、循環システムに拍動流を発生させる手段を備える。それにより、脳血管障害や腎不全などの合併症を有する患者においても、適切な臓器潅流が得られる。

【００２１】更に、好ましくは、回路内に配置される要素のうち少なくとも、血液ポンプ、血液リザーバ、人工肺、およびフィルターを一体的に組み立てて構成する。それにより、可搬性が高まる。

【００２２】更に、好ましくは、回路の流入部に配置された空気混入を検出する空気混入検出手段と、空気混入検出手段の出力に応じて作動し、回路内への空気の混入が検出されたとき、警報の発生およびポンプの自動停止のうち少なくとも一方を行う手段とを備える。それにより、空気の回路内混入という重大なトラブルを防止できて、安全性が高まる。

【００２３】

【発明の実施の形態】以下、本発明の実施の形態について、図面を参照して概略を記載する。図１に、本発明の一実施形態における体外循環装置を示す。なお、図８の従来例と同一の構成要素については、同一の番号を付したが、その配置は必ずしも従来例と同一ではない。

【００２４】脱血管２から送血管１０までの回路中には、上流（脱血管側）から下流に向かって、主要な要素として、フィルタ９、メインポンプ６、人工肺７、血液リザーバ３が配置され、それらが順次短いチューブで接続されている。血液リザーバ３、メインポンプ６にはそれぞれ、駆動装置３８ａ、駆動用モータ３８ｂが設けられている。さらに、回路の流入部（本発明で言う流入部

とは、メインポンプより上流側の血液回路の一部を指す）に、圧センサを含む回路内圧測定ポート３７、および超音波流量計プローブ３１が配置されている。３９は制御手段をなすコントローラであり、血液リザーバ３、メインポンプ６、回路内圧測定ポート３７、および超音波流量計プローブ３１と、配線４０により接続されている。１１は回路内の血液の流れを示す。

【００２５】血液リザーバ３は、貯留する容量を能動的に増減するための容量調節手段を有する。駆動装置３８ａは容量調節手段の要素の一部をなすものである。また、図１には図示されていないが、血液リザーバ３は、容量を検出するための容量検出手段を有する。回路内圧測定ポート３７、および超音波流量計プローブ３１は、回路内の循環状態を検出するための手段である。

【００２６】コントローラ３９は、回路内圧測定ポート３７および超音波流量計プローブ３１の出力に応じて、血液リザーバ３の容量およびメインポンプ６を制御する。コントローラ３９は、制御のための基準値を保有し、それに基づいた制御を行うので、基準値を設定するための設定部を有する。基準値の設定は、可変であることが望ましいが、使用の条件によっては固定であってもよい。また、コントローラ３９による制御が、回路内圧測定ポート３７および超音波流量計プローブ３１の出力により自動的に行われることは必須ではない。コントローラ３９を手動で操作する構成であっても、血液リザーバ３が容量調節手段を有することにより、本発明の効果の主要部分は得られるからである。以上の要素のうちの主要なものについて、以下に詳述する。

【００２７】＜血液リザーバ３ならびにその容量調節装置＞血液リザーバ３は、図２に示したように、血液を容れて貯めておく血液室１６と、血液室１６の内容量を調節するための圧調節室１７とを備える。両室１６，１７は、可撓性のある隔壁（ダイアフラム）１８により区切られている。３ａ、３ｂは回路と接続するための接続管、３ｃは、圧調節室１７と容量調節装置（図示せず）とを接続するための接続管である。図２には図示していないが、貯留された血液容量を検出する容量検出手段を有する。血液リザーバ３は、容量調節装置により貯血量を能動的に調節可能である。本発明における血液リザーバ３、ならびにその容量調節装置としては、様々な形態のものを用いることができる。それらを分類しながら説明する。

【００２８】一般的に体外循環回路に組み込まれる血液リザーバは、血液と空気が接する開放型と、空気と接しない閉鎖型がある。従来の体外循環装置では、開放型リザーバが組み込まれていることが多い。しかし、簡便な体外循環装置とするためには、リザーバの貯血量を常に監視しなければならない開放型のリザーバは不適である。従って、本発明では、閉鎖型が好ましい。血液室の血液容量を能動的に増減させ、調節するための容量調節装置としては、第一の、液体あるいは気体を介して血液室を圧迫牽引することにより血液容量を調節する流体圧式と、第二の、直接機械的に血液室を圧迫牽引することにより血液容量を調節する機械式とがある。

【００２９】第一の流体圧式においては、図２に示すように、血液を容れる血液室１６と、血液室の全体もしくは一部を包み込み、圧調節のための気体や液体を容れる圧調節室１７の二つの部屋が存在する。血液室１６は、容器の全体もしくは一部が軟性となっており、圧調節室１７の圧は、血液室１６の軟性部分を介して血液室１６に反映され、血液室１６の容量が調節される。図２は流体圧式の中でも、可撓性のある隔壁（ダイアフラム）１８を有する血液リザーバを示す。

【００３０】圧の媒体は気体でも液体でもよい。液体は流動性を持ったものなら何でもよい。滅菌し溶存気体を除去した脱気生理食塩水が好ましいが、血液と直接接することはないので滅菌していない単なる水でもよい。圧調節室に液体や気体等の流体を送り込み、適切な圧を発生させる血液リザーバ容量調節装置は、血液室に組み込むことも可能であるが、チューブを介して別個に設置してもよい。組み込んだ場合はシステム全体がコンパクトになる。別個にした場合は、血液室自体はコンパクトになり、血液室の設置場所の制限が少なくなる。

【００３１】血液リザーバ容量調節装置は適切な圧を発生させ得るものなら何でもよい。媒体が空気の場合には、圧の調節可能なコンプレッサーを用いることも可能である。媒体が液体の場合は、シリンジやベローズなどの直接容量を規定してしまう方式（容量規定方式）と、送液ポンプを用いて液圧を調節する方式（ポンプ液圧調節方式）がある。

【００３２】容量規定方式には、図３に示すような構造の装置を用いることができる。同図（ａ）は圧調節室の容量を、ピストン１９を用いて規定する装置を示す。ピストン１９の位置により加減される圧力が、接続管１９ａを介して圧調節室１７に伝達される。同図（ｂ）、（ｃ）、（ｄ）は、各々容量が、シリンジ２０、ベローズ２１、プッシャープレート２２により調節される。（ａ）と同様に、各々、接続管２０ａ，２１ａ，２２ａを介して圧調節室１７に接続される。ピストン１９、シリンジ２０、ベローズ２１、プッシャープレート２２は、モータ等により駆動される。

【００３３】ポンプ液圧調節方式では、圧調節室の容量は、血液リザーバ容量調節装置用の送液ポンプを用いて調節される。ここで用いるポンプは送液可能なものなら何でも適用できる。求められる性能としては、小型で信頼性、耐久性に優れ、送液の方向を問わず、応答性に優れ、高い圧が発生でき、コストのかからないものがよい。具体的には、遠心ポンプ、斜流ポンプ、軸流ポンプ、摩擦ポンプ、ギアポンプ、ローラーポンプなどが挙げられる。遠心ポンプと斜流ポンプは、送液の方向が一

方向なので、方向を変える切り替え弁が必要となる。図４（ａ）、（ｂ）はそれぞれ、ローラーポンプ２３、軸流ポンプ２４を用いた例を示す。図において、２５は送液用の貯液室である。

【００３４】第二の機械式としては、図５に示すような構成を用いることができる。この場合、血液リザーバ容量調節装置は、血液室に直接結合した構造になる。図５（ａ）は、ピストン１２を用いた例である。血液室１２ｃは、ピストン１２の位置により容量が可変の容器となる。１２ａ，１２ｂは回路と接続するための接続管である。同図（ｂ）、（ｃ）、（ｄ）は、各々容量が、シリンジ１３、ベローズ１４、プッシャープレート１５により調節される例を示す。駆動源としては、モータや電磁石などが用いられ、なんらかの圧迫牽引を受けることにより容量を調節する。

【００３５】第一の機械式と第二の流体圧式の両者において、血液室の形状は、抗血栓性を高めるため、血流鬱滞箇所の少ないものとしなければならない。機械式より流体圧式の方が血液室のデザインの制限が少なく、抗血栓性においては優れていると考えられる。一方、機械式は、機構が単純で部品点数も少なくてすむため、安価に製作可能である。血液室容量の調節範囲は、対象となる患者が成人か小児かにもよるが、成人であれば１００ｍｌ～４０００ｍｌまで調節可能であることが望ましい。

【００３６】血液室の容量を検出する容量検出手段の構成としては、様々な形態のものを用いることができる。ピストン、シリンジ、ベローズを血液室に用いれば、駆動モータの回転軸の変位位置により単純に容量を検出できる。血液室や圧調節室にホールセンサーや超音波クリスタル等の容量検知手段を取り付けたり、血液室に微弱な電流を流してインピーダンスやコンダクタンスを電流電圧計で計測するなどの方法でも血液室の容量を計測できる。また、流体圧式の場合でその流体が液である場合は、調節室からチューブを介して排出された液の容量を液量計で計測しても血液室の容量を計測できる。排出された液の容量の計測法は、自由度が高いため多くの方法が考えられるが、単純に重さを重量計で測るだけでもよい。なお、コントローラ３９に検出データを供給するための手段が必要であり、そのためには、例えば検出結果を電気信号として出力するように構成する。

【００３７】本発明における血液リザーバに、熱交換器を組み込むことは可能である。熱交換器を組み込む方法はいくつかあり、次のようなものが例として挙げられる。第一に、血液リザーバの血液室内に、熱交換能の優れた材質でできたチューブを設置し、同チューブ内に加温あるいは冷却された液体を潅流することにより、血液ひいては生体の加温、冷却が可能である。第二に、プッシャープレートを用いた機械式リザーバでは、プッシャープレートを加温あるいは冷却することにより、血液ひいては生体の加温、冷却が可能である。加温だけに限定すれば、プッシャープレートにヒーターを組み込む方法も考えられ、単純で有効な方法である。第三に、水圧式リザーバでは、圧調節室内の液を加温あるいは冷却することにより、血液ひいては生体の加温、冷却が可能である。血液室内に熱交換器を設置するより、血液の鬱滞箇所がなくなり、抗血栓性が高くなると考えられ、低侵襲性を高めるためにも有効な方法である。

【００３８】＜メインポンプ６＞次に、メインポンプ６について説明する。ＭＩＣＳなどで用いられている脱血管は細いため、適切な脱血量が得られないことがある。そのため、脱血に過大ではない適切な陰圧を付加する必要がある。落差脱血では付加陰圧に限界があるため、ポンプを用いた強制脱血が好ましい。また、落差脱血では、落差を大きくするため、手術台を高くする必要があるが、強制脱血では、心臓以外の一般の手術と同じ手術台を利用でき、手術室の運用上有効である。

【００３９】一般的に、送液ポンプには容積型と非容積型がある。体外循環装置に多く用いられているローラーポンプは容積型ポンプに分類される。体外循環装置のメインポンプに容積型ポンプを用い、しかも血液リザーバより上流に設置した場合の問題点は、脱血管に吸い付きなどの回路の障害が生じた時に、ポンプの流入部に過大な陰圧が発生することである。過大な陰圧は脱血部の生体組織を傷つけ、空気の回路内への引き込みなど重大なトラブルを引き起こす可能性がある。このため、血液リザーバより上流に設置するメインポンプの種類としては、吸い付き等が生じても過大な陰圧が発生せず、調節性に優れた非容積型ポンプが好ましい。非容積型ポンプの代表的なものは、遠心ポンプ、斜流ポンプ、軸流ポンプなどのターボ式ポンプである。このいずれも本発明には用いることができるが、軸流ポンプは高い圧を発生させるためには、回転数を極めて高くする必要があるため、溶血や耐久性を考慮すると好ましい選択ではない。よって、遠心ポンプや斜流ポンプが好ましい。

【００４０】＜コントローラ３９、および循環状態検知手段＞次に、本発明の体外循環装置におけるコントローラ３９による循環状態の制御について説明する。体外循環装置の操作を簡便にし、最も好ましくは自動制御化するために、コンピュータによる制御が必要である。制御にはいくつかの方法が考えられ、また組み合わせることも有効である。

【００４１】第１の方法は、圧による吸い付き検出と予防である。すなわち、回路の流入部圧をモニターし、圧波形から吸い付きを検出し、吸い付きが現れれば、ポンプの回転数を下げるか、もしくは血液リザーバの容量を下げる制御を行う。流入部の圧は静脈圧を反映し、正常ではほとんど脈圧のない定常流となっている。しかし、脱血管の吸い付きが生じれば、急激な圧の低下を特徴とする異常な圧波形の乱れが生じる。これは脈圧の増大や、圧変化（圧微分値の絶対値の増大）の増大、圧周波

数成分の変化となって現れる。これを循環状態検知手段を構成する圧測定ポート３７の圧センサで検出し、それによって得られた情報を制御手段であるコントローラ３９に伝達する。コントローラ３９にはコンピューターが組み込まれており、圧センサから得られた情報によって、血液が体外循環装置内を順調に流れるようにメインポンプ６および／または血液リザーバを調節する。

【００４２】第２の方法は、流入部圧の最低限界値を設定し、設定値を下回れば、ポンプの回転数を下げるか、もしくは血液リザーバの容量を下げる制御法である。最低限界値は、ある程度の陰圧はやむを得ないが、－１００ｍｍＨｇを下回るような陰圧は、メインポンプのキャビテーション発生や、予期せぬ空気の回路内への引き込みなど障害の元となるため予防しなければならない。この場合も第１の方法と同様に、循環状態検知手段としては、回路の流入部圧を計測するため、図１に示す圧センサ３７を用いる。なお、コントローラ３９には、流入部圧の最低限界値を設定する手段を備えることが必要である。

【００４３】第３の方法は、血液ポンプの消費電流もしくは電力を測定し、消費電流もしくは電力の波形から脱血部の吸い付きを検出し、吸い付きが現れれば、ポンプの回転数を下げるか、もしくは血液リザーバの容量を下げる制御法である。これは基本的には第１の方法と同じであるが、ポンプのモータが持っている内部データを用いるため特別なセンサを必要とせず、コストの削減につながる。この場合、血液ポンプを駆動している駆動装置（モータ）の消費電流や消費電力を計測しなくてはならないので、循環状態検知手段として、ポンプのモータの電流または電力をモニターする手段が必要となる。

【００４４】第４の方法は、目標となる生体の動脈圧や体外循環血液流量を設定し、該動脈圧と該流量の両者もしくはどちらか一方が設定値を下回れば、ポンプ回転数を上げるか、もしくは血液リザーバの容量を下げ、該動脈圧と該流量の両者が設定値を上回れば、ポンプ回転数を下げるか、もしくは血液リザーバの容量を上げる制御法である。設定する動脈圧や体外循環血液流量は、生体の個体差や術式、生体の状態により決定しなければならず、いかなる状況でも同じ値に設定することは考えられない。しかし、事前に個々の症例に適した目標動脈圧や体外循環血液流量を決めることは可能であり、体外循環実施中に設定値を頻回に変更する必要はない。ポンプ回転数と血液リザーバ容量のどちらを優先して調節するかは特に限定されず、どちらも可能である。

【００４５】一つの好ましい方法として、ポンプ回転数の至適上限値（Ａｒｐｍと記す）を設定し、Ａｒｐｍを越えるまでは、血液リザーバ容量を優先して容量を増やし最大とする方向（フル脱血）で制御し、血液流量を増加させるためにＡｒｐｍを越える必要が生じれば、回転数を上げずに血液リザーバ容量を減らしていくという方法が考えられる。また、体外循環中は昇圧剤や血管拡張剤の投与も必要であり、適宜適切な処置が必要となる。第４の方法の場合、体外循環装置に設ける循環状態検知手段としては、生体の動脈圧や体外循環血液流量が計測できるものならば、特に限定されず、例えば血液回路に設けた（血）圧モニターラインや血流量計等が挙げられる。

【００４６】＜回路およびシステムの簡素化＞回路を簡素化し、チューブを極力短くすることにより、体外循環回路の充填量の減少が可能となる。充填量の減少は血液希釈による浮腫の発生を抑え、輸血の必要性を大幅に低下させることにより、低侵襲性に寄与できる。また、予め製造レベルで回路を組み立てておくことにより、組み立てに必要な労力を省略し、人的省力化とコスト削減につながる。さらに、製造レベルで回路内の充填も済ませておけば、さらに術前の準備が軽減できる。また、従来の体外循環装置は大型であり、広いスペースを確保する必要があり、移動が困難なため、器材の弾力ある運用に支障を来していた。本発明では、回路および駆動装置をコンパクトに設計し、可搬性を確保することが可能であり、これらの問題も解決される。

【００４７】＜拍動および振動付加装置＞脳血管障害や腎不全などの合併症を有する患者では、拍動流を有する体外循環の有効性が認められている。よって、本発明においても、拍動および振動を付加可能とすることは、低侵襲化を図るためにも有効である。拍動および振動を付加する方法には次のようなものが考えられる。第１に、ポンプの回転数を周期的に増減させることにより、拍動流を発生させる方法である。第２に、血液リザーバの容量を周期的に増減させることにより、拍動流ないし振動を発生させる方法である。特に後者は、能動的に容量を調節できる血液リザーバの特徴を生かした新規な方法である。第１と第２の方法を併用することも可能であり、有効である。

【００４８】＜抗血栓処理＞回路の血液接触面に抗血栓性処理を施す。さらに、本発明においては、空気と接しない閉鎖式で、血流鬱滞箇所の少ない抗血栓性を高めた血液リザーバを用いるため、抗血栓性処理と相まって、より少ない抗凝固剤での体外循環が可能となる。具体的には、通常の体外循環ではヘパリンなどの抗凝固剤を投与して、活性化凝固時間を４００秒以上に保つところを、２００秒から２５０秒で運転可能とする。その結果、出血が少なくなり、手術時間の短縮や輸血の必要性の低下など、体外循環装置の低侵襲性を高めるために有効である。

【００４９】＜分離式操作パネル＞図６に一例を示すように、手術野に設置可能な分離式操作パネル２６を使用し、制御に必要な操作が手術野から可能とする。これにより、特別な体外循環操作者を設ける必要性が少なくなり、人的省力化につながる。分離式操作パネルは、タッ

チパネル式の液晶ディスプレイに透明な滅菌カバー２７を掛けたものなどが考えられる。術者２８（あるいは第一助手）の手の届くところに設置し、体外循環の監視や制御が音や音声を用いて手術をしながらでも可能となるようなユーザインターフェイスが好ましい。

【００５０】＜遠隔操作機能＞体外循環の操作が、手動から、より自動化されれば、遠隔からの監視と制御が可能となる。具体的な例を示せば、体外循環の監視と制御に必要なデータを、汎用性のある計測器と通信の規格（たとえばＧＰＩＢとＴＣＰ／ＩＰの組み合わせなど）でネットワーク上に乗せ、体外循環集中管理室で一括管理する。多数の体外循環装置が同時に運転されている大規模な病院では、人的省力化につながる有効な方法である。また、全てのデータを記録し保存することも可能となるので、学術的な活用に役立つ。

【００５１】＜回路内空気混入防止装置＞回路内への空気混入は、体外循環運転中に起こる重大なトラブルの一つである。簡便なシステムであるということは、簡便に使用できるほど安全性が高いということである。空気混入への対処法には、いくつかの方法が考えられる。第１に、体外循環血液流量をモニターする流量計として超音波流量計を用い、同流量計にバブル検出機能を持たせる。図１に示すように、超音波流量計のプローブ３１を回路の流入部に取り付け、バブルが検出されれば、直ちに警報を発し、対処する。

【００５２】第２に、回路流入部にフィルタ３２を設置する。フィルタ３２は回路のもっとも高いところに設置し、空気がたまるようにする。第３に、一例を図７に示したように、フィルタ３２に空気を検出するための光学的センサ３３を設置し、空気がたまれば、これを検出し、直ちに警報を発し、ポンプを停止させる。第４に、フィルタ３２の上部先端に空気を排出するためのポート３４を設置し、ポート３４を吸引回路３５に接続する。通常このポート３４は遮断器３６により遮断されている。フィルタ３２に空気がたまれば、直ちに手動、もしくは自動的にポートの遮断が解除され、空気が外部に吸引排出される。これらの方法の複数、あるいは全てを組み合わせることは可能であり、有効である。なお図７における３０は血液の流れを示す。

【００５３】＜周辺装置との連動＞体外循環装置には、術式によりいくつかの周辺装置が必要となる。すなわち、吸引回路、吸引回路用リザーバ、血液濃縮装置（セルセーバ、限外沪過装置）、心筋保護液回路ならびに注入装置、ベント回路などである。本発明において、これらの装置との連動を図ることは有効である。

【００５４】（より具体的な実施の形態）以下に、本発明の体外循環装置を用いる手術の一例としてＭＩＣＳ下の僧帽弁手術を前提とし、それに適した、より具体的な実施の形態について説明する。

【００５５】＜体外循環装置の構成＞回路の上流（脱血管側）から下流（送血管側）に向かって、図１に示すように、フィルタ９、ポンプ６、人工肺７、血液リザーバ３を順次短いチューブで接続する。これらは、コンパクトで充填液量の少ないものが好ましい。これらは、出荷時に既に組み立てられていると便利である。これらは、滅菌されて供給されることが好ましく、コンパクトであることと相まって、手術の滅菌術野に設置することも可能であり有効である。滅菌術野に設置できれば、脱血管や送血管と接続するためのチューブをさらに短くでき、全体の充填液量をさらに少なくできる。フィルタは、不純物の除去と、回路内に混入した空気の捕獲・遮断が目的である。空気を捕獲するために、全回路内でもっとも高い位置に設置する。

【００５６】ポンプはターボ式ポンプが好ましいが、小型の斜流ポンプであれば、さらに好ましい。ポンプを駆動するためのモータは、防水性で滅菌可能であれば滅菌術野に設置でき、取り扱いが便利である。あるいは、ポンプと同じディスポーザル製で滅菌しておれば、さらに取り扱いが便利である。人工肺はどの様なものも利用できるが、コンパクトなものが好ましい。ガス交換能や血液適合性の優れたものは、特に好ましく、この点から、気泡型より膜型がよい。血液リザーバは、貯血された血液容量を機械的に計測し、調節可能なものとする。様々な態様が考えられるが、機械式と水圧式のそれぞれについて、一例を挙げる。

【００５７】機械式はプッシャープレートを用いる。血液リザーバの血液室は硬性のハウジングと柔軟な膜からなる。血液リザーバ駆動装置は血液室の柔軟な膜を圧迫するための硬性のプッシャープレートと、プッシャープレートを圧迫・牽引するためのモータと、モータコントローラからなる。プッシャープレートは、血液リザーバの柔軟な膜を均一に圧迫できるものでなければならない。プッシャープレートが床に対して水平となるように血液リザーバを設置した方が、プッシャープレートにかかる加重が均一となり好ましい。プシャープレート内にヒーターを埋め込み、患者の体温を上げる必要が生じれば加温する。モータは回転を直線運動に変換する手段を持たなければならないが、はじめから直線運動を生じるリニアモータでもよい。モータコントローラは、主にモータの位置制御を行う。血液室の容量計測はモータの位置を検出することにより行う。

【００５８】液圧式においては、透明な硬性のプラスチック容器の内部に柔軟な隔壁（ダイアフラム）を置き、血液室と圧調節室の二つの腔を設ける。圧調節室は、接続チューブにより送液用の貯液室に接続されている。圧調節室、貯液室、接続チューブは送液用の液体（水道水を使用）で満たされている。接続チューブの途中にはローラーポンプが設置されており、ローラーポンプを正方向あるいは逆方向に回転させることにより、圧調節室の容量を調節し、その結果血液室の容量が調節される。液

圧式では血液リザーバの設置は、床に対してどの様な角度でも良く、設置の自由度が高い。圧調節室内にヒーターを埋め込み、患者の体温を上げる必要が生じれば加温する。図１に示すように、流入部には回路内圧測定ポート３７を設け、流入部回路内圧をモニターする。また、流入部に超音波流量計（バブル検出機能付き）プローブを取り付ける。

【００５９】体外循環装置に拍動流を発生させる機能を付加する。ポンプのモータの回転数と血液リザーバの容量を周期的に同期を取って変化させることにより、強力な拍動付加能力が得られる。本発明の体外循環装置各構成要素の接続順序は、従来の体外循環装置とは異なった配慮が必要である。フィルタは回路内に混入した空気の捕獲・遮断が大きな目的であるため、最上流に設置する。ポンプより上流は陰圧、下流は陽圧となっている。よって、人工肺は陽圧側に置く。血液リザーバは、陰圧、陽圧のどちら側にも設置可能であるが、前述の機械式であれば陽圧側に設置した方が好ましい。その理由は、血液室内が陽圧であれば、プッシャープレートを強制牽引する必要がなく、血液リザーバの柔軟な膜とプッシャープレートの間を接着固定する必要がなくなり、組み立て上便利である。血液リザーバを用いて拍動流を発生させるためには、血液リザーバをもっとも下流に設置することが望ましい。以上より、回路の上流（脱血管側）から下流（送血管側）に向かって、フィルタ、ポンプ、人工肺、血液リザーバの順となることが望ましい。

【００６０】体外循環装置を駆動・制御するためのコントローラに必要な機能は数多くある。この機能の中には少なくとも、ポンプモータの回転と制御、血液リザーバ駆動装置モータの駆動と制御、流入部回路内圧測定用トランスデューサとアンプ、超音波流量計（バブル検出機能付き）、分離式操作パネルとの通信、患者の血圧等の外部データ入力、システム全体の制御、などが含まれる。さらに、吸引回路、吸引回路用リザーバ、血液濃縮装置（セルセーバ、限外沪過装置）、心筋保護液回路ならびに注入装置、ベント回路などとの連動機能も有効である。また、ネットワークを介しての監視・制御データの入出力機能も有効である。同コントローラは、システムの省スペースと可搬性を高めるために、小型で移動可能なものが好ましい。

【００６１】＜手術のセッティング＞本発明の体外循環装置を構成するフィルタ、ポンプ、人工肺、血液リザーバは、出荷時に組み立て、滅菌を完了させておくことにより、短時間に滅菌手術野に設置できる。回路内の充填と空気抜きは、滅菌手術野に設置する前でも、後でも可能である。また、液漏出の発生しないシリコン製膜型肺を用いれば、出荷時にすでに充填まで完了させることも可能であり、大幅な省力化につながる。空気抜き用のポートは、フィルタと血液リザーバに設けておく。体外循環装置コントローラを手術台の近傍に設置する。流入部回路内圧をモニターし、滅菌された超音波流量計（バブル検出機能付き）プローブを取り付ける。さらに、吸引回路、心筋保護液回路などを準備する。分離式操作パネルに透明な滅菌カバーをかけ、術者の操作しやすい場所に設置する。術者、手術助手、麻酔医の協調の下に体外循環を運転する。従って、体外循環装置操作のためだけの特別な人員を配置しない。

【００６２】＜手術の実施＞本発明の体外循環装置を用いたＭＩＣＳ下の僧帽弁手術の手順を一例として挙げる。皮膚切開は極力短くし、部分的な正中胸骨切開を行い、心臓を露出する。また、右鼠径部に小切開を加え、大腿動静脈を露出する。大腿動脈に送血管を、大腿静脈から下大静脈に脱血管を挿入する。胸骨切開部から上大静脈に直接脱血管を挿入する。上大静脈と下大静脈の右心房近縁にテープによる二重のスネアを掛け、ターニケットとする。このターニケットは、静脈の陰圧による強制脱血でも空気を引き込まないよう十分に遮断ができるものでなければならない。脱血管の太さは患者により異なるが、細いものが挿入も簡単で視野の妨げにならない。上行大動脈に心筋保護液注入用のカニュラを設置する。充填され、空気抜きの終了した体外循環回路と、患者に取り付けられた送血管および脱血管を接続する。回路全体に問題がないことを確認し、体外循環を開始する。

【００６３】体外循環は基本的に自動運転可能とする。患者動脈圧が予め設定した値を下回らないことを条件に、ポンプ回転数を設定流量が得られるまで上げる。設定流量が得られれば、次に血液リザーバの容量を上げる。患者動脈圧と流量の許すかぎり血液リザーバの容量を上げていく。安定した体外循環運転が得られていることを確認し、上行大動脈を遮断し、心筋保護液を注入し、心臓を停止させる。潅流してきた心筋保護液や出血などは吸引され、吸引回路用リザーバに集められる。集められた液は血液濃縮装置（セルセーバ、限外沪過装置など）で処理され、患者に輸血される。血液濃縮装置の操作は簡単であるため、特別に訓練された体外循環技術者でなくても施行可能である。

【００６４】上下大静脈を遮断し、右心房・心房中隔切開、もしくは左房切開により僧帽弁に至る。僧帽弁手術、例えば僧帽弁置換術や僧帽弁形成術の方法は、ＭＩＣＳであっても、通常と変わらない。僧帽弁の処置終了後、心臓内の空気を十分除去し、上行大動脈遮断を解除し、心臓切開部を完全に縫合閉鎖する。上下大静脈遮断を解除し、体外循環流量を下げ、心拍動が充分であれば体外循環を終了する。体外循環からの離脱操作は、ある程度手動で行うことが必要であが、心内操作終了後であるので、術者や手術助手が施行可能である。

【００６５】＜空気混入への安全対策＞体外循環施行中の重大なトラブルに、回路内の空気混入がある。とくに、閉鎖型の血液リザーバを用いた場合は、直ちに空気

を除去しないと患者の動脈に送り込む危険性があるため問題である。空気の混入箇所は、ポンプより上流の陰圧側である。よって、陰圧側に不要なポートを設けないことが重要である。また、回路の接続部は簡単に外れないような工夫も必要である。回路自体に問題はなくとも、心臓内から脱血管に空気を引き込む可能性もある。そのため、上下大静脈の遮断は、確実なものとしなければならない。

【００６６】また、流入部回路内圧が過大な陰圧にならないようにポンプを制御し、吸い付きを予防する。これらの安全対策を行っても、空気が混入する可能性を考慮し、さらに安全機構を設ける。混入した空気は、超音波流量計のバブル検出機能により検出され、直ちに警報を鳴らし、ポンプの回転数を下げ、流量を減らす。ただし、停止はしない。ポンプの停止は、循環遮断を意味するので、安易なポンプ停止は適切な対応とは言えない。フィルターにも空気検出のセンサーを取り付け、空気が一定以上たまれば、直ちにポンプを停止させる。フィルターの上端には空気抜きのポートを設けておき、あらかじめ吸引回路を接続し、通常は遮断しておく。バブル検出機能により空気が検出されるか、フィルターに空気がたまれば、自動もしくは手動操作で、吸引回路への遮断を解除し、空気を回路外に除去する。また、血液リザーバにも、上端に空気抜きポートを設け、必要に応じ空気を抜けるようにしておく。

【００６７】

【発明の効果】本発明によれば、血液リザーバが容量調節手段と容量容量検出手段を有することにより、体外循環の制御が容易であり、装置運転の負担が軽減された体外循環装置を提供することができる。また、装置運転の自動化も可能となる。さらに、血液リザーバと血液ポンプを併せて制御することにより、血液ポンプの駆動流量を高くしても装置を安全に運転できるので、低侵襲な体外循環が可能となる。

【図面の簡単な説明】

【図１】　本発明の実施形態における体外循環装置を示す模式図

【図２】　本発明の実施形態における流体圧式容量調節血液リザーバを示す模式図

【図３】　本発明の実施形態における各種の流体（液）圧式容量調節血液リザーバの容量調節装置（容量規定方式）を示す模式図

【図４】　本発明の実施形態における各種の流体（液）圧式容量調節血液リザーバの容量調節装置（ポンプ水圧調節方式）を示す模式図

【図５】　本発明の実施形態における各種の機械式容量調節血液リザーバを示す模式図

【図６】　本発明の実施形態における分離式操作パネルの概要を示す模式図

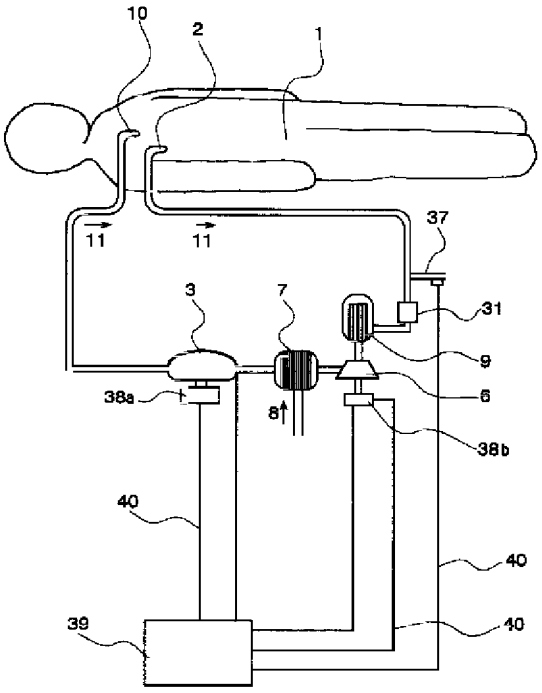
【図７】　本発明の実施形態における空気混入防止装置を示す模式図

【図８】　従来例の体外循環装置を示す模式図

【符号の説明】

２　脱血管
３　血液リザーバ
４　加温冷却装置
５　熱交換器
６　メインポンプ
７　人工肺
８　人工肺へのガスの流れ
９　フィルタ
１０　送血管
１１　回路内の血液の流れ
１２　ピストン
１３　シリンジ
１４　ベローズ
１５　プッシャープレート
１６　血液室
１７　圧調節室
１８　ダイアフラム
１９　ピストン
２０　シリンジ
２１　ベローズ
２２　プッシャープレート
２３　ローラーポンプ
２４　軸流ポンプ
２５　送液用の貯液室
２６　分離式操作パネル
２７　透明シート
３０　血液の流れ
３１　超音波流量計プローブ
３２　フィルタ
３３　光学的センサ
３４　空気を排出するためのポート
３５　吸引回路
３６　回路遮断器
３７　回路内圧測定ポート
３８ａ　駆動装置
３８ｂ　駆動用モータ
３９　コントローラ
４０　配線

【図１】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38a
8
38b
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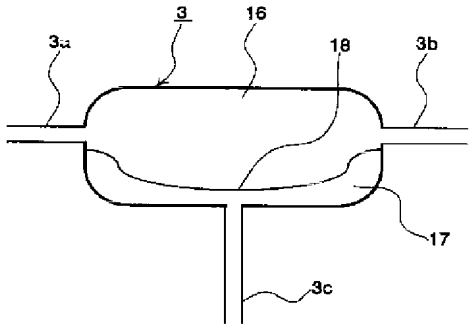
40

【図２】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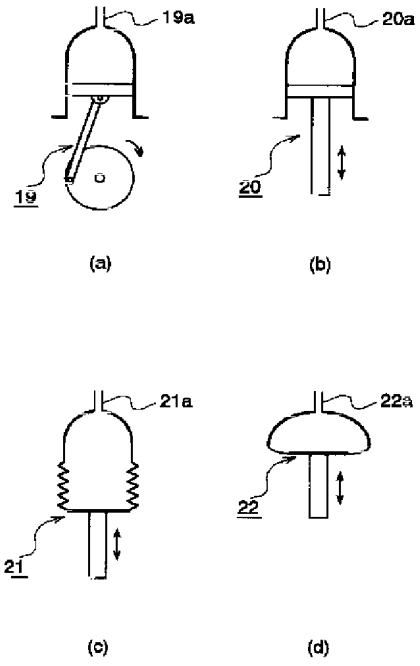
16
18
3b
17
3c

【図３】


19a
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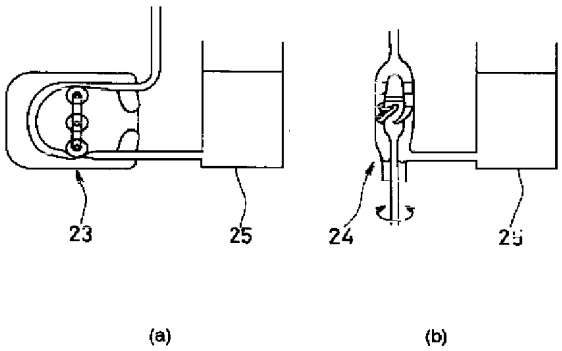
(a)
20a
20
(b)
21a
21
(c)
22a
22
(d)

【図４】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(a)
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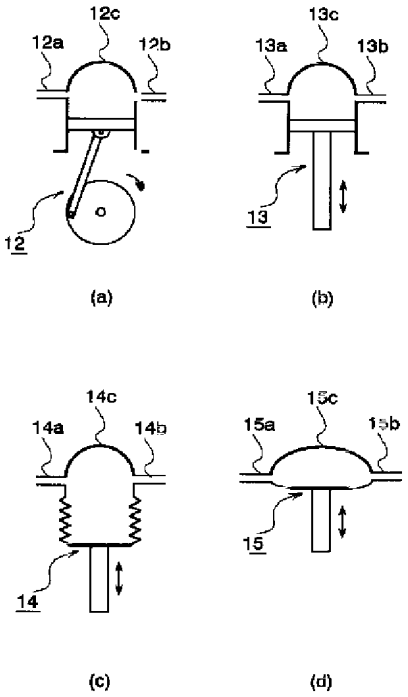
25
(b)

【図５】


12c
12a
12b
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(a)
13c
13a
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(b)
14c
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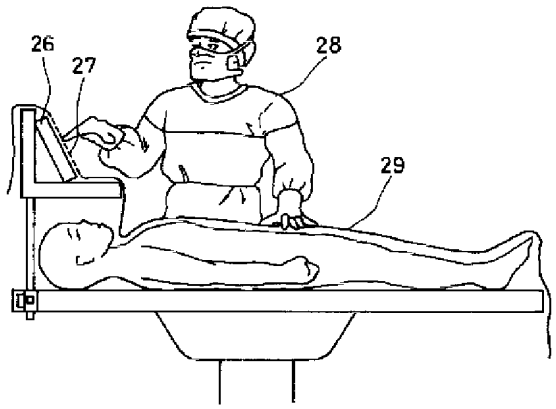
(c)
15c
15a
15b
15
(d)

【図６】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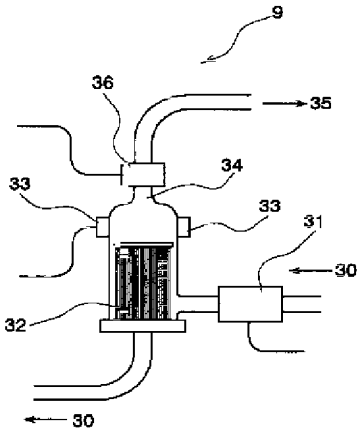
【図７】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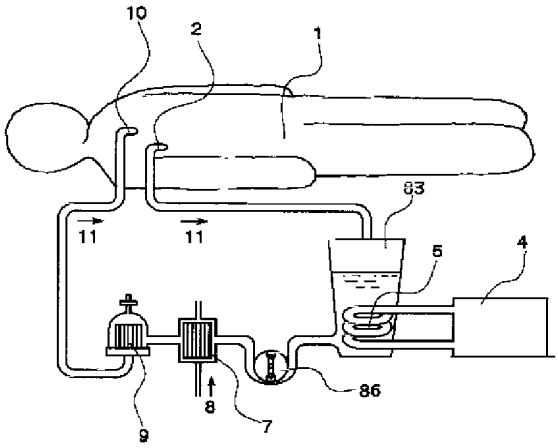
【図８】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